Supporting Statement – Part A
New Procedural Requirements beginning with FY2015 PPS-Exempt Cancer Hospital Quality Reporting Program (PCHQR Program) and Modification to OMB Approved Forms

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. We are expanding the PPS-exempt Cancer Hospital Quality Reporting Program (PCHQR) as part of our sustained efforts to improving the quality of care for inpatient cancer patients. It is our aim to facilitate high quality of care in a manner that is effective and meaningful, while remaining mindful of the reporting burden this poses on the PCHs. Therefore, CMS intends to reduce duplicative reporting efforts whenever possible by leveraging existing infrastructure.

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

Measure Steward	Quality Measures
ACoS/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	National Healthcare Safety Network (NHSN) Central Line-Associated Bloodstream Infection (CLABSI) Outcome Measure (NQF #0139)
	National Healthcare Safety Network (NHSN) Catheter-Associated Urinary Tract Infection (CAUTI) Outcome Measure (NQF #0138)

Although prior to the inception of this program, 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 ACoS/CoC. 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.

CMS is proposing to implement some procedural requirements to meet the statutory mandate by aligning with current quality reporting programs. These procedural requirements would involve submission of forms to comply with the PCHQR Program requirement and align with current CMS reporting requirements for other quality programs (i.e., Hospital Inpatient Quality Reporting, Hospital Outpatient Quality Reporting, and Hospital Value-Based Purchasing).

Last year, OMB approved the NOP, DACA, Withdrawal, Decline to Participate, and HAI Exception forms (OMB Control Number: 0938-1175). This year, we would like to modify three forms (NOP, DACA, and HAI Exception).

1) We have added information about the submitter and information on where to submit the forms to the NOP and DACA forms.
2) Additionally, we have revised the HAI exception form by deleting CLABSI and CAUTI exceptions and added other measures (e.g., NQF 0753 SSI measure).

In our effort to streamline records and leverage the Electronic Health Records (EHR) program, we have developed three online applications (NOP, DACA, and Extraordinary Circumstances Waiver). We have experienced in the past with other quality reporting program that under some unforeseen circumstances (natural disaster), hospital providers have been unable to gain access to the internet. In the event that this happens, we have developed some paper-based forms (NOP, DACA, and Extraordinary Circumstances Waiver) for the hospital providers to submit their information as required by the PCHQR Program.

Additionally, we would like to request clearance for the following additional forms: the Waiver (extraordinary circumstances) and SCIP and Oncology Care measures data collection. We have included both screenshots of the web-based tool and paper forms for these measures. The paper submission forms acts as a contingency plan if access to the internet is unavailable and hospital providers will not be unduly penalize for late submission.

For the FY 2015/FY 2016 PCHQR Program, we will continue to collect the current five measures that were used in reporting FY 2014 data (listed in the table above). We also intend to collect 14 additional NQF-endorsed measures. We have listed the proposed measures applicable beginning with FY2015 and FY2016 in the tables below. More information will be available following publication of the final rule.

Proposed Measures Beginning with FY 2015		
Measure Domain	**NQF Endorsement Number**	**Measure Name**
Patient Safety	0753	Harmonized Procedure Specific Surgical Site Infection (SSI) Outcome Measure

Proposed Measures Beginning with FY 2016		
Measure Domain	**NQF Endorsement Number**	**Measure Name**
Surgical Care Improvement Project (SCIP)	0218	Surgery Patients who Received Appropriate VTE Prophylaxis within 24 Hrs Prior to Surgery to 24 Hrs After Surgery End Time
	0284	Surgery Patients on Beta Blocker Therapy Prior to Admission who received a Beta Blocker during the Perioperative Period
	0453	Urinary Catheter Removed on Post-Operative Day 1 or Post-Operative Day 2 with Day Surgery Being Day Zero
	0527	Prophylactic Antibiotic Received Within 1 Hr Prior to Surgical Incision
	0528	Prophylactic Antibiotic Selection for Surgical Patients

	0529	Prophylactic Antibiotic Discontinued Within 24 Hrs After Surgery End Time
Clinical Process/Oncology Care	0380	Multiple Myeloma-Treatment with Bisphosphonates
	0382	Oncology-Radiation Dose Limits to Normal Tissues
	0383	Oncology: Plan of Care for Pain
	0384	Oncology: Pain Intensity Quantified
	0390	Prostate Cancer-Adjuvant Hormonal Therapy for High-Risk Patients
	0389	Prostate Cancer-Avoidance of Overuse Measure-Bone Scan for Staging Low-Risk Patients
Patient Engagement/Patient Experience of Care	0166	HCAHPS Patient Experience of Care Survey

In selecting the proposed quality measures, we strive to achieve several objectives. First, the measures should relate to the National Quality Strategy aims of better care, healthy populations and communities, and affordable care. Second, the measures should be tailored to the needs of improved quality in the inpatient cancer setting; thus, the measures selected are most relevant to PCHs. Finally, the measures should be minimally burdensome to the PCHs

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 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 the 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 that 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, the Secretary is required 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 PCHQR 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 exception/waiver form for inadequate number of cases as defined by the measure steward (e.g., CDC or CMS). PCHs experiencing low case threshold to meet the inclusion criteria, as set forth by the CDC on two (2) Health Acquired Infection (HAI) measures and one (1) Surgical Site Infection (SSI) measure, may request for a waiver to be excluded from data submission.

2. Information Users

- PCHs: The main points of focus for PCHs are to examine their individual PCH-specific care domains and types of patients so they can compare present performance to past performance and to 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 (TJC) 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 (IQR) 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 an individual hospital, allowing them to see how well patients of one facility fare compared to other facilities 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 Hospital IQR 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 the cancer hospital to further improve quality to identify the optimal practice.

3. Use of Information Technology

PCHs will be able to utilize electronic means to submit/transmit their forms and data via a CMS provided secure web-based tool which will be available on the QualityNet website. PCH users will be required to open an account to set up secure logins and then will be able to complete all the necessary forms/applications as may be applicable to their circumstance (i.e. the NOP, DACA, and Waivers). We have included copies of these forms with this package.

A Web-based Measure online tool will be used for data entry through the QualityNet website. Data will be stored to support retrieving reports for hospitals to view their measure rates/results. Hospitals will be sent a preview report via QualityNet Exchange prior to the data release on the CMS website for public viewing.

4. Duplication of Efforts

The PCHQR Program does not impose duplicate data collection. It uses elements that are currently collected by the CDC and the American College of Surgeons (ACoS) and integrating it into our current CMS's system. Currently, under the Hospital IQR program, hospitals (including some PCHs) are already submitting the CLABSI, CAUTI, and SSI measures to CDC. Additionally, some PCHs are already submitting cancer-specific measures and HCAHPS measure to ACoS and CMS. In an effort to reduce burden and minimize duplicative efforts, CMS is leveraging existing infrastructure through the CDC, ACoS's, and our own CMS infrastructures.

5. Small Business

Information collection requirements were designed to allow maximum flexibility specifically to small PCH providers participating in the PCHQR program. This effort will assist small PCH providers in gathering information for their own quality improvement efforts. For example, we will be providing a help-desk hotline for troubleshooting purposes and 24/7 free information available on the QualityNet Web site through a Questions and Answers (Q&A) function.

6. Less Frequent Collection

Unlike other existing quality reporting programs, this program is not linked to any payment penalties if quality measures are not submitted. Therefore, we propose to collect data on quarterly basis.

7. Special Circumstances

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

8. Federal Register Notice/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 ACoS) and the individual PCHs on details pertaining to the Program.

A 60-day Federal Register Notice will be included as part of the proposed regulation that is expected to be displayed in April 2013.

9. Payment/Gift to Respondent

No other payments or gifts will be given to respondents for participation.

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 Estimate (Total Hours & Wages)

Until FY2014, PCHs have not reported quality data to CMS for the PCHQR Program. However, they have reported quality measures to other entities such as state surveys and other certification organizations or to CMS through other quality reporting programs (such as Hospital IQR). Therefore, PCHs have some familiarity with and experience reporting quality data. In our burden calculation, we have included the time used for chart abstraction and for training personnel on collection of chart-abstracted data and for submitting the data through QualityNet. Because PCHs have been submitting seven of the 19 measures to CMS, the amount of training required to submit data should be reduced to training on the collection of data and submission only for the proposed (14) new measures.

The burden estimates for data collection related to the proposed measures for the PCHQR Program are calculated for the PCHs based on the following data:

- There are approximately 11 PCH facilities nationwide
- There is an average of approximately 63,468[1] cancer cases across all PCHs per year
- The average PCH facility handles 5,770 cases per year
- The average time spent per each measure per patient chart abstraction is approximately one half of an hour (based on 2007 GAO measure abstraction work effort survey – GAO-07-320)
- The time spent for abstracting each measure is 30 minutes per case (including 25 minutes of clinical time and five minutes of administrative time submitting the data)
- For 19 measures for time for abstracted is 9.5 hours per case
- This yields a total of 54,815 hours of abstraction and submission for each of the 11 facilities. The total burden hours for all 11 facilities are 602,965.

The PRA costs related to wages is based on the salary.com wage estimates for healthcare workers that are known to engage in chart abstraction (e.g., $33 hour). This calculated for the 54,815 hours for chart abstraction and data is $1,808,895 annual cost for each facility. The estimated burden for training personnel for data collection and submission for newly adopted

[1] FY2011 CMS MedPAR

measures is 7 hours per facility. The cost for this training based on an hourly rate of $33 is $231 training costs for each PCH and $2,541 training costs for all PCHs annually. The highest total burden estimates for all measure data collection and submission costs for all facilities is $19,897,845 annually, the actual expense will be incrementally increased based on the program year each measure is adopted. The total annual cost for all the facilities for training is $2,541 and the all-inclusive total is $19,900,386 (See Table A).

Table A

Tasks	**Hours per PCH**	**Wage rate**	**Cost per PCH**	**Total cost for all PCHs**
Chart Abstracted Measure Data Collection and Submission	54,815	$33	$1,808,895	$19,897,845
Training	7	$33	$231	$2,541
Total				$19,900,386

The NoP and the DACA forms are required to be filled out only once for each data submission period. All others forms are optional. It is estimated that these forms should take less than five minutes to complete thus the burden related to this activity is negligible.

13. Capital Costs (Maintenance of Capital Costs)

There are no capital costs being placed on PCHs.

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.

The labor cost for government employees to support this program is estimated below:.

- current year 1.0 FTE (2080 hours) at GS-12 salary = $83,200
- for subsequent years .254FTE (520 hours)at GS-12 salary = $20,800

15. Program or Burden Changes

The number of PCH cases is constantly changing. For the first program year data indicated approximately 2,479 cases per hospital per year. For this estimate that number has increased to 5,770. The change in burden hours from the first program year went from 68,182 to 602,965 for this year due to the increase in the number of measures included in its data collection requirements. Also, these calculations include measures for both FY2015 and FY2016.

The CMS program reduces the reporting burden for quality of care information collected by allowing hospitals to abstract data directly into electronic systems in lieu of submitting paper charts, or to utilize electronic data that they already report to other entities. The long-term vision for the PCHQR program is to allow hospitals to submit data directly from their electronic health records, which we anticipate will reduce burden substantially. The 2012 Electronic Reporting Pilot (76 FR 74490) is an important step in the transition from paper to electronic reporting.

16. Publication/Tabulation Dates

CMS will not be employing any sampling techniques or statistical methods. CMS is not the measure steward and does not have ownership of the measure specifications. However, PCHs will have to comply with the measure specifications (including sampling and validation techniques) set forth by measure stewards.

PCHs will submit their measures through a web-based measures tool on the QualityNet website. After PCHs have previewed their data and agree to publicly report their measure rates, CMS will publicly display the measure rates on the CMS Web site. The following is a tentative example of a schedule of activities to reach these objectives, more information will be known following adoption of public comments on program dates considered in the proposed rule.

04/13/2013	Proposed Rule Published
08/02/2013	Final Rule Published
10/01/2013	Measures Publicly Announced
01/01/2014	Start of Reporting Period
01/01/2014	Notice of Participation Begins
12/31/2014	End of Reporting Period
7/1/2014	Begin Data Submission
8/15/2014	End Submission Deadline
8/15/2014	Deadline to Submit Notice of Participation
Not required for FY2014	Deadline to Complete Data Accuracy Completion Agreement (DACA)
30 days	Preview Period for Public Reporting
FY 2014	Public Posting on CMS.gov

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.