Supporting Statement – Part A
New Procedural Requirements beginning with FY 2015 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 FY 2014, and for subsequent fiscal years, PPS-exempt cancer hospitals (PCHs) shall submit pre-defined quality measures to the Centers for Medicare and Medicaid Services (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.

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 three relevant measures to the American College of Surgeons (ACoS) and about 6-7 PCHs are submitting Healthcare-associated infection (HAI) measures to Centers for Disease Control/National Healthcare Safety Network (CDC/NHSN). The fact that the majority of the PCHs have demonstrated the ability to report the measures indicates the finalized policy does not significantly impact PCHs.

CMS has implemented 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).

The Office of Management and Budget (OMB) has approved the Notice of Participation (NOP), Withdrawal, Decline to Participate, Data Accuracy and Completeness Acknowledgement (DACA), and HAI Exception forms (OMB Control Number: 0938-1175). This year, we would like to modify and add several forms (e.g., NOP, DACA, Measure Exception, extraordinary circumstances exception (ECE), and data collection for Surgical Care Improvement Project (SCIP), Oncology Care Measures (OCM), and External Beam Radiotherapy [EBRT]) to assist the PCHs with data submission to fulfil program requirements.

We would like to request clearance for the following items below:

1. Program (Procedural) Requirements:
    a. NOP and DACA forms (paper based and web application): We have added information about the submitter and information on where to submit the forms to.
    b. Measure Exception form: We have revised form to reflect all applicable measures instead of just addressing CLABSI and CAUTI measures.

c. ECE (paper based and web application): Newly adopted program requirement.[1]

2. Measure Requirements:
   a. SCIP and OCM measures forms (paper based and web application): These forms reflect updated program requirements changes (e.g., sampling methodology).
   b. EBRT measure forms (paper-based and web application): Newly adopted measure and sampling methodology.

Summary details on newly submitted and re-submitted forms can be found in cross reference Appendix B (Table A).

~~For~~Based on policies included in the FY 2015~~/FY 2016 PCHQR Program~~ IPPS/LTCH final rule, we will continue to collect the current five measures that were used in reporting FY 2014 data (77 FR 53561). We also intend to collect 14 additional NQF-endorsed measures (Appendix A, Tables A-D). Information collection frequencies are reflected in Appendix B (Table B).

In addition to adding one additional measure (EBRT measure), CMS will require PCHs to adopt a sampling methodology on all payer data for the SCIP, OCM, and EBRT measures. Collecting such quality data on all payers in the PCH setting supports the CMS triple aim by informing data-driven efforts to increase transparency and access to care and to improve efficiency and quality while at the same time reducing significant burden (64% burden reduction) when the sampling approach is applied.

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 FY 2014 and each subsequent fiscal year, each PCH 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 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.

[1] Submitted under the Hospital IQR program. We are using a standard ECE form that would apply across all quality reporting programs.

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 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 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 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 and/or a PCH does not perform a specific procedure (e.g., hip/knee surgeries) as defined by the measure steward (e.g., CDC or CMS). PCHs experiencing low case thresholds to meet the inclusion criteria, as set forth by the CDC on all applicable measures may request for a waiver to be excluded from data submission.

In our effort to leverage existing quality reporting program infrastructure, we have developed online tools/applications. We have experienced in the past with other quality reporting program that under some unforeseen circumstances (natural disaster) and/or does not meet measure criteria (e.g., too few cases for reporting purposes), hospital providers have been unable to gain access to the internet (e.g., system wide shut down or upgrade/downtime) and/or provide data for submission. In the event that this happens, we have developed some paper-based forms and provide PCHs the opportunity to receive exemption for not reporting the applicable measure(s) (e.g., measure exception and ECE).

Since FY2014, CMS has finalized 18 measures. We are ~~proposing to add~~finalizing one new quality measure to the PCHQR program ~~beginning with~~in the FY ~~2017~~2015 IPPS/LTCH final rule: External Beam Radiotherapy (EBRT) for Bone Metastases. Bone metastases are a common manifestation of malignancy, with some cancer types having bone metastases prevalence as high as 70-95%[2].

EBRT can provide significant pain relief in 50-80% of patients with painful bone metastases. Although clinical guidelines recommend the use of shorter EBRT treatment courses, there has been a reluctance to adopt them, resulting in a performance gap between treatment and guidelines. Based on the clinical relevance, we believe proposing to adopt this measure is

[2] Coleman RE. Metastatic bone disease: clinical features, pathophysiology and treatment strategies. Cancer Treat Rev. 2001;27:165-176.

imperative as it supports our commitment to promoting patient safety and supporting the NQF domains. Additionally, this new measure is NQF-endorsed, thereby meeting the requirement of section 1866(k)(3)(A) of the Social Security Act.

Additionally, CMS ~~will be finalizing~~has finalized our policy requiring PCHs to submit all payer data for the SCIP and OCM measures while applying a sampling methodology when drawing the population and sample size.

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/application 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. We have included copies of these forms with this package.

A Web-based Measure tool/application 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 ACoS and integrates them into our current CMS 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 and HCAHPS measures 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. We propose to collect data on an annual basis and apply sampling methodologies to decrease burden.

7. Special Circumstances

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

8. Federal Register Notice/Outside Consultation

We have solicited comments on the program and measure requirements through the FY 2015 IPPS/LTCH PPS proposed rules and responded to those comments in the corresponding final rules.

We received overwhelming support of our sampling methodology proposal for the SCIP and OCM measures. The commenter(s) strongly encouraged us to apply the sampling methodology to the EBRT measure. After considering the feedback, we agree with the commenter(s) and subsequently decided to add sampling methodology for the EBRT measures.

Additionally, we will continue to work closely with the reporting entities (CDC and CMS contractor), Alliance for Dedicated Cancer Centers, and the individual PCHs on details pertaining to the Program.

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)

Before FY 2014, 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 associated with the ~~FY 2016~~PCHQR program requirements, 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 18 measures finalized ~~for FY 2016~~ to CMS, we believe the amount of burden related to training should be minimal.

~~Beginning with FY 2017~~As stated in the FY 2015 IPPS/LTCH final rule, we expect a significant reduction of 64% in burden as compared to the estimate described for FY 2016 because we have adopted a policy to utilize a sampling methodology in an effort to provide reasonable and reliable estimates, while reducing burden.

In our burden calculation, we estimated the time (labor hours) required for chart abstraction and data submission, population and sample size reporting, training personnel, and the burden associated with the reporting of sampling ~~data finalized beginning in FY 2017.~~approach. Our

approach in estimating burden is relatively unchanged ~~across 2016 and 2017~~ (with some exceptions). Refer to Tables D and E for a crosswalk of our calculation methodologies.

The difference in the burden reduction is based on a significant reduction in the estimated number of cases required for data abstraction as a result of our policy to adopt a sampling methodology. In ~~FY 2016~~previous years, we estimated a "worst case" scenario approach that accounts for the entire cancer population of 63,468 cancer cases[3] across all 18 measures finalized ~~beginning with FY 2016.~~. However, the FY ~~2017~~2016 burden estimate is solely based on the estimated sample size of 37,596 cases across all 19 measures finalized ~~beginning with FY 2017.~~. Accounting for sampling has significantly reduced our burden estimate by 64% between the FY ~~2016~~2015 and FY ~~2017~~2016 estimates.

Table D. Crosswalk between FY ~~2016~~2015 and FY ~~2017~~2016 Calculation Methodologies.

	FY ~~2016~~2015	FY ~~2017~~2016
Number of facilities = 11[4]	No change	No change
Number of cancer cases = 63,468[3]	No change	No change
Average cases per facility per year = 5,770	No change	No change
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).	No change	No change
Hourly wage is $33 per hour engaged in chart abstraction[5].	No change	Salary estimate is doubled*
Personnel training requires one half of an hour for each new measure and one quarter of an hour for measure maintenance of each existing measure.	No change	No change
Apply sampling methodology = maximum of five hours to tally and report.	NA	New in FY ~~2017~~2016 estimate
Account for sampling methodologies in burden estimates	NA	New in FY ~~2017~~2016 estimate

*The salary estimate is doubled beginning with FY ~~2017~~2016 calculations in order to account for overhead and fringe benefits, resulting in a total cost per hour to PCHs of $66.

[3] FY2011 PCH data. Retrieved from the CMS MedPAR database.
[4] PCHQR Program. Retrieved from the QualityNet website: https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier2&cid=1228772864217.
[5] www.salary.com (Estimates are based on base pay rate plus overhead and fringe benefits of a Registered Nurse labor skill).

Table E. PCHQR Burden Estimates Comparison between FY ~~2016~~2015 and FY ~~2017~~2016

Tasks	Hours per PCH		Total Hours for all PCHs		Year to Year net change in total hours	Cost per PCH		Total cost for all PCHs		Year to Year net change in total cost
Chart Abstracted Measure Data Collection and Submission	FY ~~2016~~2015	FY ~~2017~~2016	FY ~~2016~~2015	FY ~~2017~~2016		FY ~~2016~~2015	FY ~~2017~~2016	FY ~~2016~~2015	FY ~~2017~~2016	
	51,930	18,798	571,230	206,778	-364,452	$1,713,690	$1,240,668	$18,850,590	$13,647,348	-$5,203,242
Training	8	5	91	55	-36	$272	$330	$2,995	$3,630	$635
Sampling		5		55	55		$330		$3,630	$3,630
Administrative Forms*	0.25	0.25	3	3	0	$8	$17	$91	$182	$91
Total	51,939	18,808	571,324	206,891	-364,433	$1,713,971	$1,241,345	$18,853,676	$13,654,790	-$5,198,886

Note: *Administrative forms: NOP, DACA, Extraordinary Circumstances Exception, and measure exception forms.

We specify in the FY 2013 IPPS/LTCH PPS final rule that we require all PCHs to fulfil program requirements. These program requirements include filling out the NOP and the DACA forms on an annual basis for each data submission period. The NOP is a document filled out by PCHs pledging to participate in the PCHQR program and consenting to submit and allow public reporting of quality measures. The DACA is a form stating that the data submitted are true, accurate, and complete. All others forms are depending on the "case-by-case" situation. For example, disaster circumstances may not affect all PCHs but rather those that impacted by the applicable disaster.

It is estimated that the NOP, DACA, ECE, and measure exception forms should take less than five minutes to complete and thus the burden related to this activity is negligible. However, we have estimated these administrative forms at a conservative estimate of 15 minutes per facility per year.

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:.

- For FY 2016: 1.0 FTE (2080 hours) at GS-12 salary = $83,200
- For FY 2017: 0.5 FTE (1040 hours) at GS-12 salary = $30,438.50[6]
- For subsequent years: 0.25 FTE (520 hours) at GS-12 salary = $20,800

15. Program or Burden Changes

As shown above, this program has increased the number of measures included in its data collection requirements, from 18 quality measures to 19 quality measures ~~beginning with~~, based on policies included in the FY ~~2017 program~~2015 IPPS/LTCH final rule. However, the overall burden estimate has decreased by 364,433 hours due to the consideration of sampling methodologies which allow PCHs to report fewer than the full population size for the SCIP, OCM, EBRT, and the HCAHPS survey.

The number of PCH cases has remained constant. For the first program year data indicated approximately 2,479 cases per hospital per year. For FY ~~2017's~~2015's burden estimate that number has increased to 5,770 cases per hospital per year. The change in burden hours from the first program year went from 68,182 to ~603,000 ~~for the FY 2016 estimate~~ due to the increase in the number of measures included in its data collection requirements and our previous calculation methodology in using "worst case" scenario approach accounting for all cancer cases. The burden estimate has decreased significantly to 206,891 hours beginning with program years covered in the FY ~~2017~~2015 IPPS/LTCH final rule due to our ~~policy~~ adoption of sampling methodologies.

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.

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[6] Office of Personnel Management. *2014 General Schedule (Base).* Retrieved on March 4, 2014 from https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/2014/general-schedule/

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
2 months	Solicitation of Public Comment.
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. We also note that we believe a two year approval term is appropriate for the PCHQR program because we will be evaluating for topped out issues specifically relevant to the SCIP measures.