Supporting Statement–Part A
New Procedural Requirements beginning with FY 2019 PPS-Exempt Cancer Hospital Quality Reporting Program (PCHQR Program)

A. Background

Pursuant to section 1886(d)(1)(B)(v) of the Social Security 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 & Medicaid Services (CMS). As CMS's aim is to facilitate high quality of care in a meaningful and effective manner while simultaneously remaining mindful of the reporting burden on the PCHs, CMS intends to reduce duplicative reporting efforts whenever possible by leveraging existing infrastructure.

CMS has implemented procedural requirements that align the current quality reporting programs, including the PCHQR Program, Hospital Inpatient Quality Reporting, Hospital Outpatient Quality Reporting, and Hospital Value-Based Purchasing. These procedural requirements involve submission of forms to comply with the PCHQR Program requirements. Unlike other existing quality reporting programs, however, the PCHQR Program is not linked to any payment penalties if quality measures are not submitted.

The Office of Management and Budget (OMB) has approved the Program /Procedural Requirements forms including Notice of Participation (NOP), Data Accuracy and Completeness Acknowledgement (DACA), Measures Exception, Extraordinary Circumstances Exception (ECE), and measure data collection forms (OMB Control No.: 0938-1175).

We are updating the wage rate we use to calculate the burden to hospitals of data collection and submission required for participation in the PCHQR Program to the wage rate in use by the other CMS quality reporting programs, such as the Hospital Inpatient Quality Reporting (IQR) Program. Further, for Program Year 2020, we are implementing four (4) new measures, which CMS will calculate using administrative claims data, and removing three (3) measures that are chart-abstracted. We therefore anticipate an overall reduction in burden given that: 1) our revision of the wage rate reduces the wage rate currently used to calculate burden; 2) the four new measures are calculated using data that facilities already provide to CMS and therefore do not impose any new or additional burden on PCHs; and 3) we are removing three previously-approved chart-abstracted measures that require data collection and submission on the part of the PCHs, therefore reducing the information collection burden. Therefore, the purpose of this PRA submission is the revision of a currently-approved collection to reduce the information collection burden on the PCHs.

B. Justification

1. Need and Legal Basis

Section 1886(k)(1) of the Act states that, for FY 2014 and each subsequent fiscal year, each PCH shall submit 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. We continue to require PCHs to meet the procedures previously set forth for making public the data/measure rates submitted under the PCHQR Program.

We are adding four (4) new quality measures into, and removing three (3) existing quality measures from, the PCHQR Program in the FY 2018 IPPS/LTCH PPS Final Rule. We are implementing the following new quality measures beginning with the FY 2020 program year: 1) Proportion of Patients Who Died from Cancer Receiving Chemotherapy in the Last 14 Days of Life (NQF #0210); 2) Proportion of Patients Who Died from Cancer Admitted to the ICU in the Last 30 Days of Life (NQF #0213); 3) Proportion of Patients Who Died from Cancer Not Admitted to Hospice (NQF #0215); and 4) Proportion of Patients Who Died from Cancer Admitted to Hospice for Less Than Three Days (NQF #0216). We note that these four measures address the use of palliative and end-of-life services, which remain underutilized. By including two process measures and two intermediate clinical outcome measures related to end-of-life care in the PCHQR Program, our intent is to assess the quality of end-of-life care provided to patients in the PCH setting. We recognize that these measures may also be used in the broader population of all hospitals providing cancer care. As previously noted, these measures will be calculated by CMS using administrative claims data, and therefore do not pose any additional data collection burden on PCHs, as they already submit administrative claims data for the purpose of payment.

In addition, we are removing the following three (3) quality measures beginning no later than the FY 2020 program year: 1) Adjuvant Chemotherapy is Considered or Administered Within 4 Months (120 Days) of Diagnosis to Patients Under the Age of 80 with AJCC III (Lymph Node Positive) Colon Cancer (PCH-01/NQF #0223); 2) Combination Chemotherapy is Considered or Administered Within 4 Months (120 Days) of Diagnosis for Women Under 70 with AJCC T1c, or Stage II or III Hormone Receptor Negative Breast Cancer (PCH-02/NQF #0559); and 3) Adjuvant Hormonal Therapy (PCH-03/NQF #0220). As these measures are currently collected by the PCHs through chart abstraction, we anticipate that their removal will result in a reduction of burden on the PCHs.

As a result of these policy changes, we anticipate an overall reduction in burden for facilities.

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 as well as 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 2014, the PCHQR Program has been publicly reporting quality measures on the *Hospital Compare* website 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 those in other facilities and to state and national averages. The website presents the quality measures in consumer-friendly language and provides a tool to assist consumers in the selection of a hospital. Modeled 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 and identify optimal practice.

3. Use of Information Technology

Under OMB Control 0938-1175 (the currently approved information collection for the PCHQR Program), there is no change to the information technology use for collection of the thirteen (13) existing, finalized measures being retained in the program.

This year, we are finalizing the addition of four (4) measures to the PCHQR Program. Because these new measures are calculated by CMS using administrative claims data, we anticipate that there will be no impact on the Information Technology in use by the 11 PCHs.

This year, we are also finalizing the removal of three (3) measures from the PCHQR Program. These chart-abstracted measures require review and abstraction by the PCHs for submission and so we anticipate that their removal will result in a reduction of burden on the facilities, including those who maintain their medical records in electronic format.

4. Duplication of Efforts

Where possible, we have selected measures that are currently reported through a common mechanism for all hospitals to conduct uniform measure reporting across settings. For example, we leverage data reported to the CDC through the NHSN so as not to require duplicate reporting. The four new measures being finalized in the FY 2018 IPPS/LTCH PPS Final Rule do not duplicate efforts because they use data that facilities are already reporting to CMS as part of the claims process and do not require any additional data submission on the part of the PCHs.

5. Small Business

Information collection requirements were designed to allow maximum flexibility specifically to small PCH providers participating in the PCHQR Program. This effort assists small PCH providers in gathering information for their own quality improvement efforts. For example, we provide 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

We have designed the collection of quality of care data to be the minimum necessary for reporting of data on measures considered to be meaningful indicators of cancer patient care by the NQF, and for calculation of summary figures to be used as reliable estimates of hospital performance. Data collection may vary (monthly, quarterly, annually, etc.) based on how an individual quality measure is specified

7. Special Circumstances

There are no special circumstances.

8. Federal Register Notice/Outside Consultation

The FY 2018 IPPS/LTCH PPs Final Rule published August 14, 2017 (82 FR 37990).

We solicited comments on the program and measure requirements through the FY 2018 IPPS/LTCH PPS Proposed Rule, published on April 28, 2017 (82 FR 19796). We received one comment specific to the burden or impact of the proposals which was to encourage the most expedient removal of the three topped-out measures as possible, with the commenter noting that to do otherwise would only impose additional burden on providers.

Beyond taking this comment into consideration, we will continue to work closely with the reporting entities, represented by the Alliance for Dedicated Cancer Centers, and the individual PCHs on details pertaining to the Program.

9. Payment/Gift to Respondent

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

10. Confidentiality

All information collected under this initiative is maintained in strict accordance with statutes and regulations governing confidentiality requirements, which can be found at 42 CFR Part 480. In addition, the tools used for transmission of data are considered confidential forms of communication and are Health Insurance Portability and Accountability Act (HIPAA)-compliant.

11. Sensitive Questions

There are no sensitive questions.

12. Burden Estimate (Total Hours & Wages)

A. PCHQR Program Burden Estimate Calculations

For the PCHQR Program, the burden associated with meeting program requirements includes the time and effort associated with completing administrative requirements and collecting and submitting data on the required measures.

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

- There are 11 PCHs participating in the PCHQR Program.
- We estimate that it takes a PCH approximately 30 minutes (0.5 hours) for data collection and submission of a chart-abstracted measure.
- We estimate an hourly labor cost pursuant updated wage data released by the Burea of Labor Statistics (BLS)[1] of $36.58/hour (wage ($18.29) plus 100% fringe and overhead ($18.29), as discussed in more detail below.

Time/Number of Responses Estimates

We estimate that it takes approximately 30 minutes for a PCH to perform chart abstraction of a single patient record for collection and submit this data to CMS. We reached this number based on the 2007 GAO measure abstraction work effort survey GAO-07-320.[2] 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.

Using estimates established in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53667), we estimate the hourly burden for each PCH for the collection, submission, and training of personnel for submitting quality measure data for one (1) chart-abstracted measure is approximately 1,258.7 hours[3] per year, or 104.9 hours per month (1,258.7 hours per year / 12 months).

Hourly Labor Cost Estimate

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[1] Occupational Employment and Wages, May 2016. Available at: https://www.bls.gov/oes/current/oes292071.htm

[2] United States Government Accountability Office, "Hospital Quality Data: HHS Should Specify Steps and Time Frame for Using Information Technology to Collect and Submit Data. Report. April 2007. Available at: http://www.gao.gov/assets/260/259673.pdf.

[3] In the FY 2013 IPPS/LTCH PPS final rule (77 FR 523667), we estimated that the annual hourly burden for the collection, submission, and training of personnel for submitting all quality measure data would be approximately 6,293.5 hours per year for five (5) finalized measures. We therefore estimate the annual hourly burden for one (1) PCH to collect and submit a single chart-abstracted measure to be 1,258.7 hours (6,293.5 hours for five measures / 5 measures).

We previously used the hourly wage rate for registered nurses from www.salary.com of $33/hour to calculate the cost to PCHs of data collection and submission to the PCHQR Program. To account for fringe benefits and overhead, which can vary from institution to institution, we estimated an additional $33 for a total wage rate of $66/hour.

However, our experience working with our data analysis contractors and those performing chart abstraction indicates that this work is performed by a different labor category than we previously thought. In addition, our previous labor cost is different from those used in other quality reporting and value-based purchasing programs, and we do not believe there is a justification for these different values given the similarity in quality measures and required staff. Therefore, to align the estimated hourly labor costs (hourly wage plus fringe benefits and overhead) used to calculate burden in the PHCQR Program with those used in other CMS quality reporting programs, including the Hospital IQR Program, we revised our hourly labor cost to $32.84. Subsequently, the Bureau of Labor Statistics released updated wage information, which we are incorporating into our final rule and which further modifies the revised hourly labor cost to $36.58 (hourly wage plus fringe benefits and overhead).

This labor cost is based on the Bureau of Labor Statistics (BLS) wage for a Medical Records and Health Information Technician. The BLS describes Medical Records and Health Information Technicians as those responsible for organizing and managing health information data; therefore, we believe it is reasonable to assume that these individuals would be tasked with abstracting clinical data for submission for the PCHQR Program. According to the BLS, the median pay for Medical Records and Health Information Technicians, most recently $16.42 per hour,[4] has been further revised to a 2016 rate of $18.29 per hour[5] before inclusion of overhead and fringe benefits.

Obtaining data on overhead costs is challenging because overhead costs vary across PCHs, and cost elements assigned as “indirect” or “overhead” costs, as opposed to direct costs or employee wages, are subject to interpretation at the facility level. Therefore, we estimate the cost of overhead, including fringe benefits, at 100 percent of the median hourly wage, as is currently done in other CMS quality reporting programs. This is necessarily a rough adjustment, because fringe benefits and overhead costs vary significantly from employer to employer. Nonetheless, we believe that doubling the hourly wage rate ($18.29 x 2 = $36.58) to estimate total cost is a reasonably accurate estimation method. Accordingly, we will use an hourly labor cost estimate of $36.58 ($18.29 salary plus $18.29 fringe and overhead) for calculation of burden forthwith. We have applied this revision to our calculation of burden for this request for amendment to our existing information collection and detail the calculations below.

B. FY 2019 Program Year Wage Rate Revision

Our previously approved burden is 400,620 responses and 200,423 hours across the 11 PCHs associated with the reporting requirements for the 16 previously finalized measures for the FY 2019 program year. Using our previously approved wage and overhead rate of $66/hour[6] our

[4] https://www.bls.gov/oes/2012/may/oes292071.htm.
[5] https://www.bls.gov/ooh/healthcare/medical-records-and-health-information-technicians.htm
[6] www.salary.com (Estimates are based on base pay rate plus overhead and fringe benefits of a Registered Nurse labor skill).

previously approved cost burden is $13,227,918 (200,423 hours x $66 per hour) across the 11 PCHs. A summary of the currently approved burden is reflected in Table A.

Table A. Currently Approved Burden

Existing 16 Measures	**Per Facility**	**All Facilities**
Number of Responses	36,420	400,620 responses
Hours	18,220.27	200,423 hours
Cost ($66/hour)	$1,202,538	$13,227,918

Applying our revised wage and overhead rate of $36.58 discussed above, the revision to the previously approved cost burden is a reduction in cost across the 11 PCHs of $5,896,445, for a revised total cost burden of $7,331,473 annually (200,423 hours x $36.58 per hour). A comparison of the previously approved and the revised burden is reflected in Table B.

Table B. Burden Comparison (Previously Approved and Revised Wage Rate)

Existing 16 Measures	**Previously Approved Burden Per Facility**	**Previously Approved Burden All Facilities**	**Revised Burden Per Facility**	**Revised Burden All Facilities**
Number of Responses	36,420	400,620	36,420	400,620
Hours	18,220.27	200,423	18,220.27	200,423
Cost ($36.58/hour)	$1,202,538	$13,227,918	$666,497	$7,331,473
Change in Burden due to Wage Rate Beginning FY 2019 Program Year			**-$536,041**	**-$5,896,445**

C. FY 2020 Burden Estimate

We proposed an additional reduction to this previously approved burden in this PRA submission. Based on the FY 2013 IPPS/LTCH Final Rule (77 FR 53667) finalized estimates of the burden of collecting measure information, submitting measure information, and training personnel, we estimate the reduction in burden provided by the proposed removal of three chart-abstracted measures to be a reduction of approximately 75,119 responses across all 11 PCHs (400,620 total responses / 16 existing measures x 3 chart-abstracted measures being removed = 75,119). As compared to our previously finalized count of 400,620 responses, we estimate a revised burden of 325,501 responses total (400,620 – 75,119 = 325,501) and 29,591 responses per PCH (325,501 / 11 = 29,591). This reduction is equivalent to 3,776 hours per year (1,258.7 hours per PCH per chart-abstracted measure x 3 chart-abstracted measures) for each PCH, or an average reduction in burden of 315 hours per month per PCH (104.9 hours per month per chart-abstracted measure x 3 chart-abstracted measures). We therefore estimate a reduction in hourly burden of chart abstraction and data submission of approximately 41,536 hours per year across the 11 PCHs (3,776 fewer hours per year per PCH x 11 PCHs). This reduction in burden results in a concurrent reduction in annual labor costs of $1,519,387 (41,536 hours x $36.58 per hour) across the 11 PCHs. We further estimate a total hourly burden of 158,887 burden hours across the 11 PCHs for data collection and submission of the remaining measures (200,423 hours across all PCHs for all previously finalized measures – 41,536 hour reduction in burden across all PCHs) and a total annual labor cost for all 11 PCHs of $5,812,086 (158,887 hours x $36.58 per hour) for the FY 2020 program year. A summary of the change in burden is reflected in Table C.

Table C. Comparison of Currently Approved Burden with Proposed Reduction in Burden Due to Removal of Three (3) Chart-Abstracted Measures*

Burden	**Existing 16 Measures/ All Facilities**	**After Removal of Three Measures/ All Facilities**
Hours	200,423	158,887
Responses	400,620	325,501
Cost	$7,331,473	$5,812,086

*This comparison employs the revised wage cost of $36.58/hour.

Beginning in FY 2020, CMS is adding four (4) additional measures to the PCHQR Program that are calculated by CMS using Medicare claims data. Because they are calculated using claims data, these measures will have no burden on the 11 PCHs. Measures that are calculated using claims data rely on information submitted by the PCHs as part of their reimbursement process and are calculated by CMS, not the PCHs.

13. Capital Costs (Maintenance of Capital Costs)

There are no capital costs being placed on PCHs.

14. Cost to Federal Government

The labor cost for government employees to support this program is estimated as 0.25 FTE (520 hours) at a GS-12 salary = $20,800. [7]

15. Program or Burden Changes

We are reducing a previously approved burden. In the FY 2018 IPPS/LTCH PPS Final Rule, we are revising the wage rate used to calculate burden for the PCHQR Program. The decrease in the cost from the previous $66 hourly wage rate (wage plus overhead and fringe) to $36.58 hourly wage rate (wage plus overhead and fringe) is a reduction of $536,041 per facility and $5,896,445 for all 11 facilities. We are also removing three (3) chart-abstracted measures from the PCHQR Program, which will reduce the information collection burden on the PCHs. The change in the burden is a reduction of approximately 41,536 hours and $1,519,387 annually across all 11 facilities. Finally, while we are also adding four (4) measures, these measures are calculated by CMS using data which facilities already report as part of the claims process and are therefore not anticipated to impose any additional burden on the PCHs.

16. Publication/Tabulation Dates

Table D shows the current schedule of activities to reach these objectives.

Table D. Publication/Tabulation Dates

Date	**Activity**
04/28/2017	Proposed Rule Published
2 months	Solicitation of Public Comment.
08/xx/2017	Final Rule Published
10/01/2017	Measures Publicly Announced
01/01/2019	Start of Reporting Period
01/01/2019	Notice of Participation Begins
12/31/2019	End of Reporting Period
7/1/2020	Begin Data Submission
8/15/2020	End Submission Deadline

[7] 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/

Date	Activity
8/15/2020	Deadline to Submit Notice of Participation
30 days	Preview Period for Public Reporting

17. Expiration Date

CMS will display the expiration date on all of the forms.