

Supporting Statement – Part A
New Procedural Requirements beginning with FY 2016 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 Social Security Act as amended by section 3005 of the Patient Protection and 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 (PCHQR) Program as part of our sustained efforts to improve 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 PCHs. Therefore, CMS intends to reduce duplicative reporting efforts whenever possible by leveraging existing infrastructure.

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 requirements 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 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 No. 0938-1175).

In the previously approved information collection (OMB No. 0938-1175) the PCHQR Program required submission of 19 total quality measures. In the FY 2016 Inpatient Prospective Payment System (IPPS)/Long Term Care Hospital (LTCH) PPS the PCHQR Program finalized removal of six previously finalized Surgical Care Improvement Project (SCIP) measures and added three new healthcare associated infections (HAI) measures. With the finalization of the changes made pursuant to this Final Rule, there are a total of thirteen (13) previously finalized quality measures being retained in the PCHQR Program and three (3) new measures. Of note, these HAI measures are reported under existing Centers for Disease Control (CDC) National Healthcare Safety Network (NHSN) infrastructure pursuant to earlier OMB approval (CDC OMB No. 0920-0666). The three measures added as a result of the changes in the final rule therefore do not require new forms and do not pose additional burden, as this burden has already been estimated and approved under CDC OMB No. 0920-0666 for which data is collected in the PCHQR Program.

The purpose of this PRA submission is to provide an update of these policy changes.

Summary information on measures can be found in Appendix A (Table A). Summary details on forms for measure collection can be found in cross reference Appendix A (Table B).

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. We continue to require PCHs to meet the procedures previously set forth for making public the data/measure rates submitted under the PCHQR Program. These procedures are listed in Appendix A (Table B).

Three new quality measures will be included in the PCHQR Program as finalized in the FY 2016 Inpatient Prospective Payment System/Long-Term Care Hospital Prospective Payment System (IPPS/LTCH PPS) rule. These measures are: (1) CDC NHSN Facility-wide Inpatient Hospital onset Methicillin-resistant *Staphylococcus aureus* (MRSA) Bacteremia Outcome Measure (National Quality Forum (NQF) 1716), (2) CDC NHSN Facility-wide Inpatient Hospital-onset *Clostridium difficile* Infection (CDI) Outcome Measure (NQF 1717), and (3) CDC NHSN Influenza Vaccination Coverage Among Healthcare Personnel (HCP) (NQF 0431). These measures should have minimal impact, if any, on PCH burden, as PCHs are familiar with CDC NHSN reporting structure for Central Line-Associated Bloodstream Infection (CLABSI) and Catheter-Associated Urinary Tract Infection (CAUTI) since the FY 2014 Program and Surgical Site Infection (SSI) since the FY 2015 Program and the new quality measures have been included in CDCs data collection since March 2016.

We believe it is important to incorporate data collected by the CDC and to publish said data on MRSA (NQF 1716) in order to ensure the highest quality of care for cancer patients and continue in our effort to support the HHS' National Action Plan and the proposed 2020 goal to reduce facility-onset MRSA infections by 50% from the 2015 baseline.¹ Since our national goal to reduce the incidence of facility-onset MRSA infections overall by 25% (or 0.75 Standardized Infection Ratio (SIR)) no later than 2013 was not met, and by 2013 only a 3% overall reduction (or 0.97 SIR) had occurred, it is of great importance to continue collecting data on MRSA to reach our proposed national goal by 2020. The collection and evaluation of MRSA data allows healthcare facility staff to evaluate whether their infection control efforts need improvement and provide opportunities for facilities to compare their performance to that of other, similar facilities. Similarly, our national goal to reduce facility-onset CDI overall by 30% (or 0.70 SIR) no later than 2013 was not met, and by 2012 only a 2% reduction (or 0.98 SIR) had occurred. Therefore, it is of great importance to continue collecting data on CDI to reach our proposed national goal (a reduction of facility-onset CDY by 30%, or 0.70 SIR) from the 2015 baseline) by 2020.² Based on the clinical relevance, we believe proposing to adopt these measures is imperative as it supports our commitment to promoting patient safety and supporting the NQF domains. We also observe that persons who are infected with the influenza virus, including those with subclinical infection, can transmit influenza virus to persons at higher risk for

¹ HHS National Action Plan to Prevent Health Care-Associated Infections: Road Map to Elimination: Proposed Targets. Retrieved from <http://www.health.gov/hai/pdfs/HAI-Targets.pdf>.

² HHS National Action Plan to Prevent Health Care-Associated Infections: Road Map to Elimination: Proposed Targets. Retrieved from <http://www.health.gov/hai/pdfs/HAI-Targets.pdf>.

complications, such as immunocompromised cancer patients. Additionally, vaccination of HCP has been associated with reduced work absenteeism and fewer deaths among patients. Annual vaccination is recommended for all HCP and is a high priority for reducing morbidity associated with influenza in health care. Achieving and sustaining high influenza vaccination coverage among HCP is intended to prevent influenza infections amongst HCP and their patients, thereby reducing disease burden and health care costs. We believe it is important to incorporate data on influenza vaccination among HCP into the data reported by the PCHs in order to ensure the highest quality of care for cancer patients in our effort to support one of the Healthy People 2020 goals of immunizing 90% of HCP nationally by 2020.³ Additionally, these new measures are NQF-endorsed, thereby meeting the requirement of section 1866(k)(3)(A) of the Social Security Act.

We are also removing six SCIP measures from the PCHQR Program, which were also recently removed from the Hospital IQR Program because they were determined to be topped-out. As the PCHQR Program collection of this data relied on the infrastructure established to collect the data for the Hospital IQR Program, now that they have been removed from the Hospital IQR Program it is no longer technically feasible to collect these measures under the PCHQR Program because we cannot maintain the extensive infrastructure for the sake of eleven hospitals and because we would rather focus the use of our information technology systems on measures that are more closely linked with clinical outcomes at the PCHs. By removing these measures, we will also alleviate the maintenance costs and administrative burden for PCHs associated with reporting them.

As a result of these policy changes, we are updating our burden estimates to reflect the removal of these six measures. We note that CDC has estimated that all hospitals, including PCHs, report all three of the finalized measures, and therefore adding them to the PCHQR Program poses no burden that has not already been accounted for in an approved collection (CDC OMB No. 0920-0666).. For further information on burden impact see section 12.

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

³ Healthy People 2020. Immunization and Infectious Diseases. Retrieved from <http://www.healthypeople.gov/2020/topics-objectives/topic/immunization-and-infectious-diseases/objectives>.

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* Web site available to consumers on www.Medicare.gov. The Web site 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 compare to other facilities and to the state and national average. The Web site 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 to identify the optimal practice.

3. Use of Information Technology

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

4. Duplication of Efforts

To minimize the duplication of efforts, CMS will receive data reported on the 3 new measures from the CDC, who currently collects data for the new measures which are being reported through The National Healthcare Safety Network (CDC NHSN), which is a large surveillance system owned by CDC for all hospitals to conduct uniform measure reporting across settings. We will leverage data reported to the CDC through the NHSN and not require duplicate reporting. This means the PCHQR Program will use the data that has already been reported via other requirements, meaning the hospitals will only have to submit data once.

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

Quality programs, such as Hospital Inpatient Quality Reporting (IQR), Outpatient Quality Reporting (OQR) and others, are all voluntary programs, that is to say, they are not required under the Medicare Conditions of Participation (CoP). These voluntary programs include the PCHQR Program; however unlike the other existing quality reporting programs, this program is not linked to any payment adjustments if quality measures are not submitted. For data reported under the PCHQR Program, we strive to balance the need to provide information on quality of care to PCH patients with the need to minimize the burden on facilities. To this end, for the majority of PCHQR measures, we require yearly data submission.

7. Special Circumstances

PCHs must abide by the reporting procedures set forth by the Centers for Disease Control and Prevention (CDC) and CMS to collect information on the 3 data measures currently collected under 0920-0666 beginning with the FY 2018 Program.

8. Federal Register Notice/Outside Consultation

We solicited comments on the program and measure requirements through the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24591-93; 80 FR 24619); <https://www.federalregister.gov/select-citation/2015/08/17/42-CFR-412> and responded to any relevant comments in the subsequent corresponding final rule (80 FR 49717-18; 80 FR 49764); <https://www.gpo.gov/fdsys/pkg/FR-2015-08-17/pdf/2015-19049.pdf>.

Additionally, we continue to work closely with the following reporting entities:

Centers for Disease Control and Prevention (CDC)

National Center for Emerging and Zoonotic Infectious Diseases
1600 Clifton Road Atlanta GA 30329-4027 USA
Telephone: 1-800-CDC-INFO (800-232-4636)
Email: CDC-INFO

Alliance of Dedicated Cancer Centers

Executive Director
Karen Bird
Phone: 617-312-5236

All 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)

Based on the previously approved information collection (OMB No. 0938-1175), for which the PCHQR Program required submission of 19 total quality measures the previously approved burden is 413,556 responses for a total of 206,891 hours across the 11 PCHs.⁴ Based on our previously approved estimate of \$66/hour labor rate, this equates to an annual burden of \$13,654,806 across the 11 PCHs.

Our new proposal reflects a burden calculation that represents the burden removed from the program by removing the six surgical care improvement project (SCIP) measures. The burden for the addition of three measures has been accounted for by CDC in the existing OMB No. 0920-0666 data collection.⁵

Overall the burden change is created by removing six SCIP measures (Table A shows the information that was used in calculating the decrease in burden.

Hourly wage is \$33 per hour engaged in chart abstraction ⁶ .
Estimated cost is \$66 per hour due to overhead and fringe benefits.
Cost = \$11/facility/year (\$121 for all facilities)

Table A. Decrease in Burden (removal of six Surgical Care Improvement Project (SCIP) measures)⁷

	Per Facility	All Facilities
Number reported per measure quarterly	49 (Based on sampling)	539
6 SCIP measures	294/quarter	3,234/quarter
4 Quarters/year	1,176 cases	12,936 cases
0.5 hours per case	588 hours	6,468 hours
\$66 dollars per hour	\$38,808	\$426,888

Table B. Total Requested Burden (previously approved burden minus overall decrease in burden for all facilities)

	Previously Approved Burden	Newly Requested Burden
Number of responses	413,556 responses	400,620 responses ⁸

⁴ Office of Information and Regulation Affairs. View Information Collection (IC). Retrieved from http://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=201401-0938-010.

⁵ In the FY 2016 IPPS/LTCH PPS Final Rule (80 FR 49764), we calculated the burden associated with one of these three measures because we understand that facilities are already collecting the other two measures. The burden we calculated (10 minutes per facility, for a total of 110 minutes across all PCHs) is already accounted for by the CDC, and therefore not included here.

⁶ www.salary.com (Estimates are based on base pay rate plus overhead and fringe benefits of a Registered Nurse labor skill).

⁷ These values represent burden removed from the program, and are therefore negative

⁸ 413,556 – 12,936 = 400,620

Hours	206,891 hours	200,423 hours ⁹
-------	---------------	----------------------------

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 = \$20,800.¹⁰

15. Program or Burden Changes

As described in Table B (see Section 12) the total change in burden based on the changes finalized in the FY 2016 IPPS/LTCH PPS final rule (deletion of six measures) are to decrease responses by 12,936 responses per year, which equates to a decrease of 6,468 hours per year.

The overall decrease in cost to all facilities is \$426,888 per year or \$38,808 per facility.

16. Publication/Tabulation Dates

The following is the schedule of activities to reach these objectives of meeting the measure specifications set forth by the CDC and other measure stewards pursuant to the final rule:

04/13/2015	Proposed Rule Published
2 months	Solicitation of Public Comment.
08/17/2015	Final Rule Published
10/01/2015	Measures Publicly Announced
01/01/2016	Start of Reporting Period
01/01/2016	Notice of Participation Begins
12/31/2016	End of Reporting Period
7/1/2017	Begin Data Submission
8/15/2017	End Submission Deadline
8/15/2017	Deadline to Submit Notice of Participation
30 days	Preview Period for Public Reporting
FY 2018	Public Posting on CMS.gov

17. Expiration Date

CMS will display the expiration date.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

⁹ 206,891 – 6,468 = 200,423

¹⁰ 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/>

There are no exceptions to the certification.