

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 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.

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 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 (Office of Management and Budget (OMB) Control Number: 0938-1175).

This year, we propose to remove six previously finalized Surgical Care Improvement Project (SCIP) measures and add three new healthcare associated infections (HAI) measures. These HAI measures are reported under existing Centers for Disease Control (CDC) National Healthcare Safety Network (NHSN) infrastructure. The three measures added as a result of the changes in the proposed rule do not require new forms as they are already reported under CDC OMB 0920-0666. Therefore the purpose of this PRA submission is to provide an update of these policy changes (add three HAI measures and remove six SCIP measures).

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).

We are adding three new quality measures to the PCHQR program in the FY 2015 IPPS/LTCH rule: (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 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 FY 2014 Program and Surgical Site Infection (SSI) since FY 2015 Program.

We believe it is important to collect 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 will allow healthcare facility staff to evaluate whether their infection control efforts need improvement. 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 CDI 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 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 collect data on this influenza vaccination among healthcare personnel 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 healthcare personnel nationally by 2020.³

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>.

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

Additionally, these new measures are NQF-endorsed, thereby meeting the requirement of section 1866(k)(3)(A) of the Social Security Act.

We are proposing to remove six SCIP measures from the PCHQR Program because we have removed them from the Hospital IQR Program and, because they have been removed from that program, it is no longer technically feasible to collect these measures under the PCHQR Program. By removing these measures, we also would 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 6 measures and the impact of the 3 added measures. 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 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 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

Under OMB Control 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.

This year, we propose to add three measures to the PCHQR Program. We leverage with the CDC NHSN's information technology to collect these three measures, which have been reported under OMB Control 0920-0666.

4. Duplication of Efforts

The additions to the PCHQR Program do not impose duplicate data collection. We have selected measures that are currently reported through a common mechanism (CDC NHSN) 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.

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.

For the three measures being proposed please see CDC's information collection request (OMB Control Number 0920-066) for information about the frequency of collection. This ICR explains the importance of frequent collection to ensure patient safety and explains how the CDC balanced this important patient safety concern with the frequency of data collection. The result of this analysis is to require at least quarterly reporting of the CDI and MRSA measures and annual reporting of Influenza Vaccination for Healthcare Professionals. As iterated in the background, the three measures added as a result of the changes in the proposed rule do not require new forms as they are already collected under CDC OMB 0920-0666.

7. Special Circumstances

PCHs will have to abide with the reporting procedures set forth by the CDC and the CMS to collect measures beginning with FY 2018 Program.

8. Federal Register Notice/Outside Consultation

We are soliciting comments on the program and measure requirements through the FY 2016 IPPS/LTCH PPS proposed rule and will respond to those comments in the corresponding final rule.

Additionally, we will continue to work closely with the reporting entities (CDC), 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)

Our previously approved burden is 413,556 responses for a total of 206,891 hours across the 11 PCHs.⁴ A summary of currently approved burden are reflected in Table A.

Table A Currently Approved Burden

	Inventory as of this Action	Requested	Previously Approved
Expiration Date	11/30/2016	24 Months From Approved	12/31/2015
Responses	413,556	63,470	27,273
Time Burden (Hours)	206,891	602,965	68,182
Cost Burden (Dollars)	0	0	0

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 and adding three CDC NHSN measures. As two of the CDC NHSN measures are already reported under OMB 0920-0666, we refer readers to the CDC's documentation for the burden estimate for these two measures. The burden for the third is calculated in the method outlined in the FY2016

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.

LTCH/IRF final rule (79 FR 50444). The information collection instruments for this form are provided in OMB 0920-0666, however PCHs may not be currently submitting information on this measure to the CDC, so we have added the burden for this measure to our estimate.

Overall the burden change is created by deleting six SCIP measures and adding one CDC NHSN measure (as the other two are already collected by the CDC). Table B shows the information that was used in calculating the increase in burden and Table C shows the information that was used in calculating the decrease in burden. Table D shows the overall burden decrease for the program. Table E shows the results of decrease in burden to the previously approved burden.

Table B. Increase in Burden (addition of 3 NHSN CDC measures)

Number of facilities = 11 ⁵
The time spent submitting the influenza vaccination for healthcare personnel measure is 10 minutes per facility, this includes training and administrative time. (1.83 hours for all facilities)
See CDC request with OMB control number 0920-0666 for information about submission of Facility-wide Inpatient Hospital-onset Methicillin-resistant Staphylococcus aureus (MRSA) Bacteremia Outcome Measure and Facility-wide Inpatient Hospital-onset <i>Clostridium difficile</i> Infection (CDI) Outcome Measure
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 C. Decrease in Burden (removal of six Surgical Care Improvement Project (SCIP) measures)

	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 D. Overall Decrease in Burden (addition of three CDC NHSN measures and removal of six SCIP measures)

	Per Facility	All Facilities
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⁵ PCHQR Program. Retrieved from the QualityNet website: <https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier2&cid=1228772864217>.

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

Number of responses	1,175 responses ⁷	12,925 responses
Hours	587.83 hours ⁸	6,466.17 hours
Cost Burden	\$38,797 ⁹	\$426,767

Table E. 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	400,631 responses ¹⁰
Hours	206,891 hours	200,424.83 hours ¹¹

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 = \$20,800.¹²

15. Program or Burden Changes

As described in Table D (see Section 12) the total change in burden based on the changes proposed in this year's rule are to decrease responses by 12,925 responses per year, which equates to a decrease of 6466.17 hours per year (Refer to Form 83, Part II, Table 3).

The overall decrease in cost to each facility is \$426,767 per year.

16. Publication/Tabulation Dates

The new measures are maintained by the CDC as the measure steward. PCHs will be expected to comply with the measure specifications set forth by the CDC as the steward for these measures.

Measures being retained in the program have several measure stewards who each maintain ownership of measure specifications. PCHs will be expected to comply with measure specifications set forth by these measure stewards.

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.

⁷ 1,176 - 1 = -1,175 cases

⁸ 588 - 0.167 = -587.83 hours

⁹ 587.833*\$66/hour = 38,797

¹⁰ 413,556 - 12,925 = 400,631

¹¹ 206,891 - 6,466.17 = 200,424.83

¹² 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/>

04/13/2015	Proposed Rule Published
2 months	Solicitation of Public Comment.
08/02/2015	Final Rule Published
10/01/2015	Measures Publicly Announced
01/01/2017	Start of Reporting Period
01/01/2017	Notice of Participation Begins
12/31/2017	End of Reporting Period
7/1/2018	Begin Data Submission
8/15/2018	End Submission Deadline
8/15/2018	Deadline to Submit Notice of Participation
30 days	Preview Period for Public Reporting
FY 2019	Public Posting on CMS.gov

17. Expiration Date

There are no new forms associated with this update, therefore no expiration date is requested.