

Supporting Statement–Part A
Quality Measures and Procedures for the PPS-Exempt Cancer Hospital Quality Reporting Program (PCHQR Program) for the FY 2021 Program Year

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 burden estimate methodology we use to calculate the burden to hospitals of data collection and submission required measures that are web-based and/or that are structural. Further, for Program Year 2020, we are implementing one (1) new measure, which CMS will calculate using administrative claims data, and removing six (6) measures: four that are web-based, structural measures, and two that are National Healthcare Safety Network (NHSN) measures, 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 proposing to add one (1) new quality measure into, and remove six (6) existing quality measures from the PCHQR Program in the FY 2019 IPPS/LTCH PPS Proposed Rule.

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

To assist hospitals in standardizing data collection initiatives across the industry, CMS continues to improve data collection tools in order to make data submission easier for hospitals (e.g., the

collection of electronic patient data in EHRs for eCQMs, the collection of data from paper medical records for chart-abstracted measures, or the collection of data from clinical registries for structural measures), as well as increase the utility of the data provided by the hospitals.

For the claims-based measures, this section is not applicable, because claims-based measures can be calculated based on data that are already reported to the Medicare program for payment purposes. Therefore, no additional information technology will be required of hospitals for these measures.

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) measures that would exist in the program if our policies are finalized as proposed.

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 new measure being proposed in the FY 2018 IPPS/LTCH PPS Proposed Rule does not duplicate efforts because it uses data that facilities are already reporting to CMS as part of the claims process and does 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

A 60-day *Federal Register* notice of the FY 2019 IPPS/LTCH PPS proposed rule published on May 7, 2018 (83 FR 20164). Comments will be submitted on this notice, and we will respond to those comments accordingly.

CMS is supported in this initiative by The Joint Commission, National Quality Forum (NQF), Measure Applications Partnership, Centers for Disease Control and Prevention, and Agency for Healthcare Research and Quality. These organizations collaborate with CMS on an ongoing basis, providing technical assistance in developing and/or identifying quality measures, and assisting in making the information accessible, understandable, and relevant to the public.

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 for Quality Improvement Organizations, 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. The CMS clinical data warehouse also voluntarily meets or exceeds the HIPAA standards.

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 are proposing that it takes a PCH approximately 15 minutes (0.25 hours) for data collection and submission of structural measures and measures that utilize a web-based tool
- We estimate an hourly labor cost (wage plus fringe and overhead) of \$36.58/hour, in accordance with the Bureau of Labor Statistics, as discussed in more detail below.

We note that our estimates exclude burden associated with the NHSN measures: (1) Healthcare-Associated Infection (HAI) Surgical Site Infection (SSI) (NQF #0753); (2) Facility-Wide Inpatient Hospital-Onset Methicillin-Resistant *Staphylococcus aureus* (MRSA) Bacteremia Outcome Measure (NQF #1716); (3) Facility-Wide Inpatient Hospital-Onset *Clostridium difficile* Infection (CDI) Outcome Measure (NQF #1717); (4) Influenza Vaccination Coverage Among Healthcare Personnel (HCP) (NQF #0431); (5) Catheter-Associated Urinary Tract Infection (CAUTI) Outcome Measure (NQF #0138); and (6) Central Line-Associated Bloodstream Infection (CLABSI) Outcome Measure (NQF #0139), which are submitted separately under OMB control number 0920-0666. These estimates also exclude the burden associated with the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) measure, which is submitted separately under and OMB control number 0938-0981.

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-07-320.¹ 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.

Hourly Labor Cost Estimate

According to the 2016 BLS rate, the median pay for Medical Records and Health Information Technicians is \$18.29 per hour² before inclusion of overhead and fringe benefits. 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. 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 \times 2 = \36.58) to estimate total cost is a reasonably accurate estimation method. Accordingly, to align the estimated hourly labor costs (hourly wage plus fringe benefits and overhead) used to calculate burden in the PHCQR Program with those

¹ 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>.

² <https://www.bls.gov/ooh/healthcare/medical-records-and-health-information-technicians.htm>

used in other CMS quality reporting programs, including the Hospital IQR Program, in the FY 2018 IPPS/LTCH PPS Final Rule, we revised our hourly labor cost to \$36.58 (82 FR 38505).

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.

B. FY 2021 Burden Estimate

a. Clarification of NHSN Measure Burden Calculations

We wish to reconcile our burden estimates to account for the prior inclusion of the burden data associated with the NHSN measures. In the FY 2016 IPPS/LTCH PPS final rule, we noted that “...all burden associated with the three measures (MRSA, CDI, and HCP measures) that we are finalizing, including the burden associated with the activities mentioned by the commenter, has been accounted for under the OMB control number 0920– 0666.” (80 FR 49764). We also note that although it was not explicitly stated in that rule, the SSI measure is also accounted for under OMB control number 0920-0666.³ As such, we wish to correct the inclusion of the burden associated with these measures under OMB control number 0938-1175, and request that in this PRA package the burden hours associated with all six of the NHSN measures in the PCHQR measure set be reduced from the overall program burden total.

In the FY 2018 IPPS/LTCH PPS final rule, “Supporting Statement-A” file, we accounted for the burden of chart-abstracted measures utilizing the same per-measure burden hour figure that we applied to the CAUTI and CLABSI measures in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53667).⁴ Specifically, we noted that 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.⁵ Because this burden estimate was derived based on NHSN measures (CAUTI and CLABSI), and previously applied to other chart-abstracted measures, we believe that it is appropriate to apply this estimate (rounded to 1,259 hours) to the proposed reduction of the administrative burden associated with the NHSN measures. We estimate this would result in a burden reduction of 7,554 hours per year (1,259 hours per measure x 6 NHSN measures) = **7,554 hours per year, per PCH**, or an average reduction in burden of 687 hours per month (7,554 hours / 12 months per year) per PCH. We note that we previously included the burden associated with reporting these six (6) NHSN measures in previous PRA package estimates in order to be as conservative as possible in our estimates. We are removing the burden associated with these measures here to improve the accuracy of our total estimated burden, and again note the burden associated with reporting these measures is and will continue to be captured under a separate OMB control number, 0920-0666.

³ NHSN Measures Supporting Statement-A file for OMB control number 0920-0666. Published on January 1, 2018. Available at: https://www.reginfo.gov/public/do/PRAViewDocument?ref_nbr=201801-0920-008

⁴ FY 2019 Final Rule Supporting Statement-A file for OMB control number 0938-1175. Published on March 20, 2018. Available at: https://www.reginfo.gov/public/do/PRAViewDocument?ref_nbr=201709-0938-005

⁵ 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).

b. Burden Calculations for the Proposed Removal of Web-Based Structural Measures

We are proposing to remove four web-based, structural measures for the FY 2021 program year: (1) Oncology: Radiation Dose Limits to Normal Tissues (PCH-14/NQF #0382); (2) Oncology: Medical and Radiation – Pain Intensity Quantified (PCH-16/NQF #0384); (3) Prostate Cancer: Adjuvant Hormonal Therapy for High Risk Patients (PCH-17/NQF #0390); and (4) Prostate Cancer: Avoidance of Overuse of Bone Scan for Staging Low-Risk Patients (PCH-18/NQF #0389). Based on these proposals, we also estimate a reduction of 1 total hour per year (15 mins per measure x 4 web-based, structural measures = **1 hour per PCH**) = **1 total annual hour for each PCH**, or an average reduction in burden of .08 hours per month (1/12 = .08) per PCH.

c. Response Calculations for Remaining PCHQR Measures

We proposed an additional reduction to this previously approved burden in this PRA submission. Consistent with the calculation methodology utilized to derive estimates of the burden of collecting measure information, submitting measure information, and training personnel, in the most recently approved PRA package⁶, we estimate the reduction in burden provided by the proposed removal of four web-based structural measures to be a reduction of approximately 217,001 responses across all 11 PCHs (325,501 total responses previously finalized /6 existing measures x 4 measures being removed = 217,001). As compared to our previously finalized count of 325,501 responses, we estimate a revised burden of 108,500 responses total (325,501 – 217,001 = 108,500) and 9,864 responses per PCH (108,500 / 11 = 9,864).

d. Summary

We therefore estimate a reduction in hourly administrative burden and data submission of web-based structural measures to be approximately 83,105 hours per year across the 11 PCHs. We note that 11 hours are based on policy proposals and the remaining 83,094 hours are due to administrative/corrective changes. This reduction in burden results in a concurrent reduction in annual labor costs of \$3,039,981 (83,105 hours x \$36.58 per hour) across all 11 PCHs. We further estimate a total hourly burden of 75,782 burden hours across the 11 PCHs for data collection and submission of the remaining measures (158,887 hours across all PCHs for all previously finalized measures – 83,105 hour reduction in burden across all PCHs = 75,782 hours) and a total annual labor cost for all 11 PCHs of \$2,772,106 (75,782 hours x \$36.58 per hour) for the FY 2021 program year. A summary of the change in burden is reflected in Table A.

Table A. Comparison of Currently Approved Burden with Proposed Reduction in Burden Due to Removal of Four (4) Web-based Structural Measures and Two (2) Chart-Abstracted Measures

Burden	FY 2020 Program Year: 18 Measures/All Facilities	FY 2021 Program Year: 13 Measures/All Facilities
Hours	158,887	75,782
Responses	325,501	108,500
Cost	\$5,812,086	\$2,772,106

⁶ FY 2019 IPSS/LTCH PPS Final Rule PRA Revision Submission. OMB Control Number 0938-1175: “Supporting Statement-A” Accessed on 1/9/2018. Available at: https://www.reginfo.gov/public/do/PRAViewDocument?ref_nbr=201709-0938-005

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. We are proposing to remove four (4) web-based structural measures and two (2) NHSN measures from the PCHQR Program, which will reduce the information collection burden on the PCHs. We are also accounting for the additional removal of the administrative burden imparted by the inclusion of the additional NHSN measures (SSI, CDI, MRSA, and HCP) under OMB control number 0938-1175. If finalized as proposed, the change in the burden is a reduction of approximately 83,105 hours ([1 fewer hour per year per PCH for the proposed removal of the web-based structural measures + 7,554 fewer hours per year per PCH for the removal of NHSN measure administrative burden] x 11 PCHs) across all 11 PCHs annually, and approximately \$3,039,981 (83,105 hours per PCH x \$36.58 wage) annually across all 11 PCHs.

We reiterate, that while we are proposing the removal of 2 NHSN measures, the burden changes associated with the proposed removal of these measures is assessed separately, under OMB control number 0920-0666.

Beginning in FY 2021, CMS is adding one (1) additional measure to the PCHQR Program. Because this measure is calculated using claims data, it will have no burden impact 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.

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

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

Table E shows the proposed schedule for publicly reporting measures in the PCHQR Program.

Table E. Proposed Public Display Requirements for the FY 2021 Program Year

Summary of Newly Proposed Public Display Requirements	
Measures	Public Reporting
<ul style="list-style-type: none"> ● HCAHPS (NQF #0166) ● Oncology: Plan of Care for Pain – Medical Oncology and Radiation Oncology (NQF #0383) 	2016 and subsequent years
<ul style="list-style-type: none"> ● American College of Surgeons – Centers for Disease Control and Prevention (ACS-CDC) Harmonized Procedure Specific Surgical Site Infection (SSI) Outcome Measure [currently includes SSIs following Colon Surgery and Abdominal Hysterectomy Surgery] (NQF #0753) ● National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset Methicillin-resistant <i>Staphylococcus aureus</i> Bacteremia Outcome Measure (NQF #1716) ● National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset <i>Clostridium difficile</i> Infection (CDI) Outcome Measure (NQF #1717) ● National Healthcare Safety Network (NHSN) Influenza Vaccination Coverage Among Healthcare Personnel (NQF #0431) 	*Proposed for Deferral Until Calendar Year 2019
<ul style="list-style-type: none"> ● External Beam Radiotherapy for Bone Metastases (EBRT) (NQF #1822) 	2017 and subsequent years

17. Expiration Date

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