Supporting Statement–Part A
Quality Measures and Procedures for the PPS-Exempt Cancer Hospital Quality Reporting Program (PCHQR Program) for the FY 2023 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 finalizing the refinement of two existing measures: (1) Catheter-Associated Urinary Tract Infection (CAUTI) Outcome Measure (NQF #0138); and (2) Central Line-Associated Bloodstream Infection (CLABSI) Outcome Measure (NQF #0139), for the FY 2023 Program Year. We note that our proposals for the FY 2023 Program Year, will not yield any net change in burden on the PCHs. Further, we note that as stated below in section 12.A, estimates for the PCHQR Program exclude burden associated with the NHSN measures, which are submitted separately under OMB control number 0920-0666.

The purpose of this PRA submission is to revise the currently approved information collection request. Specifically, we will modify the currently approved information collection request to reflect an updated burden cost, based on an increase in the labor wage.[1]

[1] The most recent data from the Bureau of Labor Statistics reflects a median hourly wage of $19.40 per hour for a Medical Records and Health Information Technician professional. Occupational Employment and Wages. Available at: https://www.bls.gov/ooh/healthcare/medical-records-and-health-information-technicians.htm

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 finalizing the refinement of two (2) existing quality measures in the PCHQR Program in the FY 2021 IPPS/LTCH PPS Final Rule for the FY 2023 Program Year.

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 fifteen (15) measures that would exist in the program.

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 existing measures being finalized for refinement in the FY 2021 IPPS/LTCH PPS Final Rule do not duplicate efforts because it uses data that facilities are already reporting to CMS as part of the NHSN 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 30-day *Federal Register* notice of the FY 2021 IPPS/LTCH PPS Final Rule (85 FR 58432) was published on September 18, 2020

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 estimate 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 $38.80[2]/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 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.[3] 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 Bureau of Labor Statistics rate, the median wage for Medical Records and Health Information Technicians is $19.40 per hour[4] 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

[2] Occupational Employment and Wages. Available at: https://www.bls.gov/ooh/healthcare/medical-records-and-health-information-technicians.htm
[3] 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.
[4] Occupational Employment and Wages. Available at: https://www.bls.gov/ooh/healthcare/medical-records-and-health-information-technicians.htm

employer. Nonetheless, we believe that doubling the hourly wage rate ($19.40 x 2 = $38.80) to estimate total cost is a reasonably accurate estimation method. Accordingly, we will use an hourly labor cost estimate of $38.80 ($19.40 salary plus $19.40 fringe and overhead) for calculation of burden forthwith.

B. FY 2023 Program Year Burden Estimate

a. Burden Calculations for the Refinement of Existing NHSN Measures

We are finalizing the refinement of two NHSN measures. We note that this refinement poses no change in burden for the PCHQR Program for Program Year 2023.

b. Response Calculations for Remaining PCHQR Measures

There will be no change to the previously approved burden hours or number of respondents (outlined in Table A. below) in this PRA submission. As such, based on our proposals in the FY 2021 IPPS/LTCH PPS final rule, the burden hours for the PCHQR Program for the FY 2023 Program Year will be consistent with the most recently approved PRA package[5]. We note that there will be a change in burden cost based on an updated labor wage. We denote this update in Table A. below.

c. Summary

We therefore estimate a total hourly burden of 75,779 burden hours across the 11 PCHs for data collection and submission and a total annual labor cost for all 11 PCHs of $2,940,225 (75,779 hours x $38.80 per hour) for the FY 2023 program year. A summary of the change in labor cost is reflected in Table A.

Table A. Comparison of Currently Approved Burden with Finalized Burden Due to Refinement of Two NHSN Measures

Burden	**FY 2022 Program Year: 15 Measures/All Facilities**	**FY 2023 Program Year: 15 Measures/All Facilities**
Hours	75,779	75,779
Responses	142,406	142,406
Cost	$2,853,837	$2,940,225*

***Note:** *The increase in cost is a function of the modified labor wage, as outlined by the Bureau of Labor Statistics*.[6]

13. Capital Costs (Maintenance of Capital Costs)

There are no capital costs being placed on PCHs.

[5] FY 2020 IPPS/LTCH PPS Final Rule PRA Revision Submission. OMB Control Number 0938-1175: *"Supporting Statement-A"* Accessed on 1/8/2020. Available at: https://www.reginfo.gov/public/do/PRAViewDocument?ref_nbr=201910-0938-003

[6] Occupational Employment and Wages. Available at: https://www.bls.gov/ooh/healthcare/medical-records-and-health-information-technicians.htm

14. Cost to Federal Government

The labor cost for government employees to support this program is estimated as 0.25 FTE at a GS-12 step 5 salary = $24,462.[7]

15. Program or Burden Changes

Beginning in FY 2023 Program Year, CMS is finalizing the refinement of two existing measures to the PCHQR Program. This proposal will have no burden impact on the 11 PCHs. We note that there will be a change in burden cost based on an updated labor wage. We denote this update in Table A., in section B.12.B.b above.

16. Publication/Tabulation Dates

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

Table B. Publication/Tabulation Dates

Date	Activity
05/29/2020	Proposed Rule Published
2 months	Solicitation of Public Comment
09/2/2020	Final Rule Published
10/01/2020	Measures Publicly Announced
01/01/2020	Start of Reporting Period
01/01/2020	Notice of Participation Begins
12/31/2020	End of Reporting Period
7/1/2021	Begin Data Submission
8/15/2021	End Submission Deadline
8/15/2021	Deadline to Submit Notice of Participation
30 days	Preview Period for Public Reporting

Table C shows the finalized schedule for publicly reporting measures in the PCHQR Program.

Table C. Finalized Public Display Requirements for the FY 2023 Program Year

Summary of Newly Finalized Public Display Requirements	
Measures	**Public Reporting**
● HCAHPS (NQF #0166) ● Oncology: Plan of Care for Pain – Medical Oncology and Radiation Oncology (NQF #0383)	2016 and subsequent years
● American College of Surgeons – Centers for Disease Control and Prevention (ACS-CDC) Harmonized Procedure Specific Surgical Site Infection (SSI) Outcome Measure	As soon as feasible

[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/

Summary of Newly Finalized Public Display Requirements	
Measures	**Public Reporting**
[currently includes SSIs following Colon Surgery and Abdominal Hysterectomy Surgery] (NQF #0753) ● National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset Methicillin-resistant *Staphylococcus aureus* Bacteremia Outcome Measure (NQF #1716) ● National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset *Clostridium difficile* Infection (CDI) Outcome Measure (NQF #1717) ● National Healthcare Safety Network (NHSN) Influenza Vaccination Coverage Among Healthcare Personnel (NQF #0431)	
● Admissions and Emergency Department (ED) Visits for Patients Receiving Outpatient Chemotherapy	April 2020
● CAUTI (NQF #0138) ● CLABSI (NQF #0139)	Deferred until CY 2023

17. Expiration Date

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