Supporting Statement–Part A
Quality Measures and Procedures for the PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program for the FY 2024 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, Hospital Inpatient Quality Reporting, Hospital Outpatient Quality Reporting, and Hospital Value-Based Purchasing Programs. 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).

In the FY 2022 IPPS/LTCH PPS final rule, we finalized the adoption of one new measure and the removal of one existing measure from the PCHQR Program measure set. First, we adopted the COVID-19 Vaccination Coverage Among Healthcare Personnel (COVID-19 HCP Vaccination) measure beginning with a reporting period from October 1, 2021 through December 31, 2021, affecting the FY 2023 program year, followed by quarterly reporting deadlines. The data for this measure will be reported through the CDC's National Healthcare Safety Network (NHSN). Currently, the CDC does not estimate burden for COVID-19 vaccination reporting under either the CDC PRA OMB control number 0920-1317 or 0920-0666 because the agency has been granted a waiver under Section 321 of the National Childhood Vaccine Injury Act (NCVIA). When the waiver expires, we will work with CDC to ensure that this burden is accounted for under their PRA package. Second, we removed the Oncology: Plan of Care for Pain – Medical Oncology and Radiation Oncology (National Quality Forum (NQF) #0383/PCH-15) measure beginning with the FY 2024 program year. Detail regarding the reduction in burden associated with removal of this measure is included in section 12. Further, we note that as stated below in section 12, estimates for the PCHQR Program exclude burden associated with six NHSN measures, which are submitted separately under OMB control number 0920-0666, and the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) measure, which is submitted separately under OMB control number 0938-0981.

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 updated burden estimates, based on the FY 2022 IPPS/LTCH PPS final rule and an increase in the labor wage.

B. Justification

1. Need and Legal Basis

Section 1886(k)(1) of the Social Security 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.

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 monitor quality improvement outcomes continuously over time and assess their own strengths and weaknesses in the clinical services they provide objectively; 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 and can also be used to improve PCHs' financial planning and marketing strategies.

- State Agencies/CMS: Agency profiles are used 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: In November 2014, the PCHQR Program began publicly reporting quality measures on the *Hospital Compare* website, now called *Care Compare*, available to consumers on www.Medicare.gov. On December 1, 2020, CMS relocated PCH data to the Provider Data Catalog (PDC). The PDC site can be accessed at https://data.cms.gov/provider-data/. 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. 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.

Since we finalized the removal of the last chart-abstracted, structural, or web-based measure (Oncology: Plan of Care for Moderate to Severe Pain – Medical Oncology and Radiation Oncology (NQF #0383) (PCH-15)), we recognize that the remaining measures for which collection is assessed under OMB Control 0938-1175 (the currently approved information collection for the PCHQR Program) will no longer require the use of information technology to report for FY 2024 program year and subsequent years.

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 finalized new measure in the FY 2022 IPPS/LTCH PPS Final Rule does not duplicate efforts because it uses data that facilities would report to the CDC as part of the NHSN process and does not require any additional data submission directly to CMS 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 website 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 2022 IPPS/LTCH PPS proposed rule (86 FR 25070) was displayed on April 27, 2021. Comments were submitted on this notice, and we responded to those comments in the FY 2022 IPPS/LTCH PPS final rule published on August 13, 2021 (86 FR 44774).

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 $41.00/hour, in accordance with the Bureau of Labor Statistics, as discussed in more detail below.

Table A summarizes the currently approved set of measures for the PCHQR program.

Table A. Currently Approved PCHQR Measure Set for the FY 2023 Program Year

Measure name	Measure Type
Central Line-Associated Bloodstream Infection Outcome Measure (CLABSI) (NQF # 0139) (PCH-4)	NHSN
Catheter-Associated Urinary Tract Infection Outcome Measure (CAUTI) (NQF #0138) (PCH-5)	NHSN
Harmonized Procedure Specific SSI Outcome Measure (NQF #0753) (PCH-6 [colon] and PCH-7 [hysterectomy])	NHSN
Facility-wide Inpatient Hospital-onset Clostridium difficile Infection (CDI) Outcome Measure (NQF #1717) (PCH-26)	NHSN
Facility-wide Inpatient Hospital-onset Methicillin-resistant Staphylococcus aureus (MRSA) Bacteremia Outcome Measure (NQF #1716) (PCH-27)	NHSN
Influenza Vaccination Coverage Among Healthcare Personnel (HCP) (NQF #0431) (PCH-28)	NHSN
Oncology: Plan of Care for Moderate to Severe Pain – Medical Oncology and Radiation Oncology (NQF #0383) (PCH-15)*	Web-based
Proportion of Patients Who Died from Cancer Receiving Chemotherapy in the Last 14 Days of Life (EOL-Chemo) (NQF #0210) (PCH-32)	Claims-based
Proportion of Patients Who Died from Cancer Not Admitted to Hospice (EOL-Hospice) (NQF #0215) (PCH-34)	Claims-based
Proportion of Patients Who Died from Cancer Admitted to the Intensive Care Unit (ICU) in the Last 30 Days of Life (EOL-ICU) (NQF #0213) (PCH-33)	Claims-based
Proportion of Patients Who Died from Cancer Admitted to Hospice for Less Than Three Days (EOL-3DH) (NQF #0216) (PCH-35)	Claims-based
HCAHPS Survey (NQF #0166) (PCH-29)	Survey
Admissions and Emergency Department (ED) Visits for Patients Receiving Outpatient Chemotherapy (PCH-30 and PCH-31)	Claims-based
30-Day Unplanned Readmissions for Cancer Patients (NQF #3188) (PCH-36)	Claims-based
Surgical Treatment Complications for Localized Prostate Cancer (PCH-37)	Claims-based
COVID-19 HCP Vaccination**	NHSN

** Measure removed beginning with FY 2024 in the FY 2022 IPPS/LTCH PPS final rule.*
***Measure finalized for adoption beginning with FY 2023 in the FY 2022 IPPS/LTCH PPS final rule.*

We note that our estimates exclude burden associated with the six previously approved NHSN measures, which are submitted separately under OMB control number 0920-0666. These estimates also exclude the burden associated with the recently finalized COVID-19 HCP Vaccination Measure. As mentioned above, the CDC currently does not estimate burden for COVID-19 vaccination reporting under either the CDC PRA OMB control number 0920-1317 or 0920-0666 because the agency has been granted a waiver under Section 321 of the National Childhood Vaccine Injury Act (NCVIA). When the waiver expires, we will work with CDC to ensure that this burden is accounted for under their PRA package. Additionally, these estimates 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. Finally, we do not include burden associated with claims-based measures as these measures are calculated using claims data submitted by the PCHs as part of their reimbursement process and are calculated by CMS, not the PCHs. As a result, the only measure for which burden is accounted for under this PRA is Oncology: Plan of Care for Moderate to Severe Pain – Medical Oncology and Radiation Oncology (NQF #0383) (PCH-15) which has been finalized for removal beginning with the FY 2024 program year as discussed 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 estimate 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. 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.

Hourly Labor Cost Estimate

According to the Bureau of Labor Statistics (BLS) rate, the median wage for Medical Records and Health Information Technicians is $20.50 per hour[2] before inclusion of overhead and fringe benefits. This labor cost is based on the 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.

[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] Bureau of Labor Statistics, Occupational Employment and Wages. Accessed on February 12, 2021: https://www.bls.gov/ooh/healthcare/medical-records-and-health-information-technicians.htm.

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 ($20.50 x 2 = $41.00) to estimate total cost is a reasonably accurate estimation method. Accordingly, we will use an hourly labor cost estimate of $41.00 ($20.50 salary plus $20.50 fringe and overhead) for calculation of burden forthwith.

B. FY 2024 Program Year Burden Estimate

a. Correction to Currently Approved Burden Estimates

A review of the measure set for the PCHQR program for the FY 2023 program year indicates that the currently approved burden is overestimated. The overestimation originated in the FY 2019 IPPS/LTCH PPS final rule PRA Supporting Statement A for OMB 0938-1175, wherein we addressed the incorrect prior inclusion of burden data associated with NHSN measures (which are covered under OMB 0920-0666) and the HCAHPS measure (which is covered under OMB 0938-0981) and updated burden estimates to account for the finalized removal of web-based measures.[3] The FY 2019 IPPS/LTCH PPS final rule PRA Supporting Statement A ultimately overcalculated the number of measures that are not claims-based, and therefore overestimated the burden included in that PRA.[4] This overcalculation was then carried forward into the FY 2020 IPPS/LTCH PPS final rule PRA Supporting Statement A for OMB 0938-1175[5] and the FY 2021 IPPS/LTCH PPS final rule PRA Supporting Statement A for OMB 0938-1175,[6] resulting in continued overestimation of burden.

The currently approved burden for the PCHQR program for the FY 2023 program year is 75,779 hours at a cost of $2,940,225 (75,779 hours x $38.80/hour). As discussed, the currently approved burden hours are incorrectly based on an overestimated assumption of the total number of chart-abstracted measures, structural measures, and measures that utilize a web-based tool.[7] Upon review of the measure set for the PCHQR program currently approved for the FY 2023 program year as shown in Table A, including the eight measures accounted for under OMB control number 0938-1175, the total number of chart-abstracted measures, structural measures, and measures that utilize a web-based tool is 1 (Oncology: Plan of Care for Moderate to Severe

[3] 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, https://www.reginfo.gov/public/do/PRAViewDocument?ref_nbr=201812-0938-018.

[4] As previously mentioned, we do not include burden associated with claims-based measures in burden estimates because these measures are calculated using claims data submitted by the PCHs as part of their reimbursement process and therefore do not result in additional reporting burden for the PCHs.

[5] Supporting Statement – Part A Quality Measures and Procedures for the PPS-Exempt Cancer Hospital Quality Reporting Program (PCHQR Program) for the FY 2022 Program Year, https://www.reginfo.gov/public/do/PRAViewDocument?ref_nbr=201910-0938-003.

[6] 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 https://www.reginfo.gov/public/do/DownloadDocument?objectID=105411000.

[7] Supporting Statement – Part A Quality Measures and Procedures for the PPS-Exempt Cancer Hospital Quality Reporting Program (PCHQR Program) for the FY 2022 Program Year, https://www.reginfo.gov/public/do/DownloadDocument?objectID=95901701.

Pain – Medical Oncology and Radiation Oncology (NQF #0383) (PCH-15)). The other seven measures are claims-based measures. As a result, the currently approved burden estimate should be decreased to 3 hours (11 PCHs x 0.25 hours) at a cost of $116 (3 hours x $38.80/hr).[8] As a result, the total burden decrease is estimated to be 75,776 hours (75,779 hours – 3 hours) and a decrease in cost of $2,940,109 ($2,940,225 - $116).

b. Burden Calculations for the Removal of One Measure

We finalized the removal of the Oncology: Plan of Care for Pain – Medical Oncology and Radiation Oncology (NQF #0383/PCH-15) measure beginning with the FY 2024 program year. As previously discussed, we utilize a time estimate of 15 minutes per measure when assessing web-based and/or structural measures. As such, we estimate that the removal of this measure from the PCHQR measure set will result in a reduction of 15 minutes (0.25 hours) per PCH per year, with a total annual reduction in reporting burden across all PCHs of 3 hours (0.25 hours x 11 PCHs) and a total annual reduction in cost across all PCHs of $123 (3 hours x $41.00/hr), beginning with the FY 2024 program year.

There will be no additional changes to the previously approved burden hours or number of respondents in this PRA submission.

c. Summary

We estimate a total hourly burden of 0 burden hours across the 11 PCHs for data collection and submission and a total annual labor cost for all 11 PCHs of $0 for the FY 2024 program year. A summary of the change in labor cost is reflected in Table B.

Table B. Comparison of Currently Approved Burden with Finalized Burden Due to Corrections and Removal of One Measure

Burden	**FY 2023 Program Year: 16 Measures/All Facilities**	**FY 2024 Program Year: 15 Measures/All Facilities**
Hours	75,779	0
Responses	142,406	0
Cost	$2,940,225	$0

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 at a GS-12 step 5 salary = $24,707.[9]

[8] The currently approved burden was also included in the FY 2022 IPPS/LTCH PPS Proposed Rule when describing the effects of the proposed requirements on the PCHQR Program. Upon review, as described herein, we discovered that the burden described in this PRA package is more accurate. We included an explanation of this error in the FY 2022 IPPS/LTCH PPS final rule.

15. Program or Burden Changes

We are revising the total number of measures for which burden is accounted for under this PRA from 7 to 1. As a result, the total estimated burden will decrease from 75,779 hours at a cost of $2,940,225 (75,779 x $38.80) to 3 hours at a cost of $116. The updated labor wage from $38.80/hour to $41.00/hour results in a total increase of $7 for all 11 PCHs to a total burden estimate of $123. Beginning in the FY 2024 program year, CMS has finalized the removal of one existing measure to the PCHQR Program. This provision results in a total decrease of 3 hours at a cost of $123 for 11 PCHs. As a result, we estimate a total burden of 0 hours at a cost of $0 for the FY 2024 program year.

16. Publication/Tabulation Dates

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

Table C. Publication/Tabulation Dates

Date	Activity
05/10/2021	Proposed Rule Published
2 months	Solicitation of Public Comment
08/1/2021	Final Rule Published
01/01/2022	Start of Reporting Period
12/31/2022	End of Reporting Period
30 days	Preview Period for Public Reporting

CMS posts measure submission deadlines on the QualityNet website (https://qualitynet.cms.gov/pch/pchqr).
Table D shows the previously finalized schedule for publicly reporting measures in the PCHQR Program.

Table D. Public Display Requirements for the FY 2024 Program Year

Summary of Finalized Public Display Requirements	
Measures	**Public Reporting**
● HCAHPS (NQF #0166)	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 [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*	2019 and subsequent years

[9] Office of Personnel Management. *2021 General Schedule.* Retrieved on April 21, 2021 from https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/21Tables/html/DCB.aspx

Summary of Finalized Public Display Requirements	
Measures	**Public Reporting**
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 and subsequent years
● CAUTI (NQF #0138) ● CLABSI (NQF #0139)	Deferred until CY 2022
● COVID-19 HCP Vaccination*	CY 2022

**Measure adopted beginning with the FY 2023 program year.*

17. Expiration Date

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

18. Certification Statement

We are not claiming any exceptions to the Certification for Paperwork Reduction Act Submissions Statement.