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

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 proposing to adopt one (1) new measure, which CMS will calculate using administrative claims data, and proposing to remove one (1) web-based, structural measure for Program Year 2022. The purpose of this PRA submission is to revise a currently-approved information collection request. This revison modifies 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 adopt one (1) new quality measure and proposing to remove one (1) existing quality measure from, the PCHQR Program in the FY 2020 IPPS/LTCH PPS Proposed Rule for Program Year 2022.

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 new measure being proposed for adoption in the FY 2020 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 2020 IPPS/LTCH PPS Proposed Rule (insert cite upon publication) was displayed on April XX, 2019.

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 $37.66[1]/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*

[1] The most recent data from the Bureau of Labor Statistics reflects a median hourly wage of $18.83 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

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.[2] 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 Statisitics rate, the median wage for Medical Records and Health Information Technicians is $18.83 per hour[3] 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 ($18.83 x 2 = $37.66) to estimate total cost is a reasonably accurate estimation method. Accordingly, we will use an hourly labor cost estimate of $37.66 ($18.83 salary plus $18.83 fringe and overhead) for calculation of burden forthwith.

B. FY 2022 Program Year Burden Estimate

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

We are proposing the removal of one web-based, structural measure for the FY 2022 program year: External Beam Radiotherapy (EBRT) for Bone Metastases (formerly NQF #1822). Based on this proposed removal, we estimate a reduction of .25 total hours per year (15 mins per

[2] 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.

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

measure x 1 web-based, structural measure = **.25 hours per PCH**) =**.25 total annual hours for each PCH**, or an average reduction in burden of .02 hours per month (.25/12 = .02) per PCH.

b. Response Calculations for Remaining PCHQR Measures

We are proposing an additional reduction to this previously approved burden (outlined in Table A. below) 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 package[4], we estimate the reduction in burden provided by the removal of one web-based structural measures to be a reduction of approximately **20,344 responses across all 11 PCHs** (162,750 total responses previously finalized /8[5] existing measures x 1 measures being removed = 20,344). As compared to our previously finalized count of 162,750 responses, we estimate a revised burden of **142,406 responses total** (162,750 – 20,344 = 142,406) and 12,946 responses per PCH (142,414 / 11 = 12,946).

c. Summary

We therefore estimate a reduction in hourly administrative burden and data submission of the proposed removal of one web-based structural measure to be approximately **3 hours per year across the 11 PCHs** (.25hrs per PCH x 11 PCHs = 3hrs). This reduction in burden results in a concurrent reduction in annual labor costs of $113 (3 hours x $37.66 per hour) across all 11 PCHs. We further estimate a total hourly burden of **75,779 burden hours across the 11 PCHs** for data collection and submission of the remaining measures (75,782 hours across all PCHs for all previously finalized measures – 3 hour reduction in burden across all PCHs = 75,779 hours) and a total annual labor cost for all 11 PCHs of $2,853,837 (75,779 hours x $37.66 per hour) for the FY 2022 program year. We note that the proposed addition of one claims-based measure (Surgical Treatment Complications for Localized Prostate Cancer) will have no burden impact on the 11 PCHs. 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 One (1) Web-based Structural Measure

[4] FY 2020 IPPS/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

[5] We note that based on our finalized policies, there will be 15 measures remaining in the PCHQR Program, however, only 8 of those measures are accounted for under OMB control number 0938-1175. As mentioned in section B.12.A above, 6 (NHSN) of the 15 remaining measures are accounted for under OMB control number 0920-0666 and the HCHAPS measure is accounted for under OMB control number 0938-0981.

Burden	FY 2021 Program Year: 15 Measures/All Facilities	FY 2022 Program Year: 15 Measures/All Facilities
Hours	75,782	75,779
Responses	162,750	142,406
Cost	$2,772,106	$2,853,837*

*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.

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 the removal of one (1) web-based structural measure from the PCHQR Program, which will reduce the information collection burden on the PCHs. The change in the burden associated with these finalized policies is a reduction of approximately 3 hours (.25 fewer hours per year per PCH for the proposed removal of the web-based structural measure x 11 PCHs) across all 11 PCHs annually, and approximately $113 (.25 hours per PCH x 11 PCHs x $37.66 wage) annually across all 11 PCHs.

Beginning in FY 2022, CMS is proposing to add 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 B shows the current schedule of activities to reach these objectives.

Table B. Publication/Tabulation Dates

Date	Activity
04/xx/2019	Proposed Rule Published
2 months	Solicitation of Public Comment
08/xx/2019	Final Rule Published
10/01/2017	Measures Publicly Announced
01/01/2019	Start of Reporting Period

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

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

Table C. Proposed Public Display Requirements for the FY 2022 Program Year

Summary of Newly Proposed 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
● External Beam Radiotherapy for Bone Metastases (EBRT) (NQF #1822)*	2017 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 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)	October of CY 2019
● Admissions and Emergency Department (ED) Visits for Patients Receiving Outpatient Chemotherapy	CY 2020
● CAUTI (NQF #0138) ● CLABSI (NQF #0139)	Deferred until CY 2022

17. Expiration Date

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