**Supporting Statement – Part A**

**Submission of Information for the Rural Emergency Hospital Quality Reporting (REHQR) Program: CY 2024 OPPS/ASC Proposed Rule**

1. **Background**

The Centers for Medicare & Medicaid Services’ (CMS’) quality reporting programs promote higher quality, more efficient healthcare for Medicare beneficiaries by collecting and reporting on quality-of-care metrics. This information is made available to consumers, both to inform Medicare beneficiaries, as well as to incentivize healthcare facilities to make continued improvements.

Specifically, CMS has implemented quality measure reporting programs for multiple settings, including for rural emergency hospital departments, to achieve its overarching priorities and initiatives, including the National Quality Strategy[1](#_bookmark0) and Meaningful Measure 2.0 Framework.[2](#_bookmark1) In particular, Meaningful Measures 2.0 promotes innovation and modernization of all aspects of quality to better address health care priorities and gaps, emphasize digital quality measurement, and promote patient perspectives by supporting five interrelated goals: (1) empower consumers to make good health care choices through patient-directed quality measures and public transparency, (2) leverage quality measures to promote health equity and close gaps in care, (3) streamline quality measurement, (4) leverage measures to drive outcome improvement through public reporting and payment programs, and (5) improve quality measure efficiency by transitioning to digital measures and using advanced data analytics.

The Rural Emergency Hospital Quality Reporting (REHQR) Program was established under the Consolidated Appropriations Act (CAA) 2021. CMS has proposed to begin data collection under this program in calendar year (CY) 2024. As required by authorizing statute, these data will be made publicly available after providing REHs the opportunity to review their data. There are no payment penalties or determinations associated with the program; however, similar to the PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program, REHs are statutorily obligated to report quality measure data. This new information collection request is intended to cover proposals in the CY 2024 OPPS/ASC proposed rule for the REHQR Program.

# Justification

* 1. **Need and Legal Basis**

Section 125 of Division CC of the CAA was signed into law on December 27, 2020, and establishes REHs as a new Medicare provider type. Section 125 of the CAA added section 1861(kkk) to the Social Security Act (the Act), which sets forth the requirements for REHs. In order to become an REH, section 1861(kkk)(3) of the Act requires that the facility, on the date of

1 https[://w](http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/CMS-)ww.[cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/CMS-](http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/CMS-) Quality-Strategy

2 https://[www.cms.gov/medicare/meaningful-measures-framework/meaningful-measures-20-moving-measure-](http://www.cms.gov/medicare/meaningful-measures-framework/meaningful-measures-20-moving-measure-) reduction-modernization

enactment of the CAA, 2021 (December 27, 2020), was a critical access hospital (CAH) or a rural hospital with not more than 50 beds. For the purpose of REH designation, section 1861(kkk)(3)(B) defines rural hospital as a subsection (d) hospital (as defined in section 1886(d)(1)(B) of the Act with not more than 50 beds located in a county (or equivalent unit of local government) in a rural area (as defined in section 1886(d)(2)(D) of the Act)), or treated as being located in a rural area pursuant to section

1886(d)(8)(E) of the Act.

Additionally, section 1861(kkk)(2) of the Act defines an REH as a facility that is enrolled in the Medicare program as an REH; does not provide any acute care inpatient services (other than post-hospital extended care services furnished in a distinct part unit licensed as a skilled nursing facility (SNF)); has a transfer agreement in effect with a level I or level II trauma center; meets certain licensure requirements; meets requirements of a staffed emergency department; meets staff training and certification requirements established by the Secretary of the Department of Health and Human Services (the Secretary); and meets certain conditions of participation (CoPs) applicable to hospital emergency departments and CAHs with respect to emergency services.

Section 125(a)(1) of the CAA further added section 1861(kkk)(1) of the Act, which requires that REHs provide emergency department services and observation care and, at the election of the REH, other medical and health services furnished on an outpatient basis, as specified by the Secretary through rulemaking. The REH must also have a staffed emergency department 24 hours a day, 7 days a week, have a physician, nurse practitioner, clinical nurse specialist, or physician assistant available to furnish REH services in the facility 24 hours a day, and meet applicable staffing requirements similar to those for CAHs.

Furthermore, section 1861(kkk)(7) of the Act requires the Secretary to establish quality measurement reporting requirements for REHs, which may include claims-based outcome measures and/or patient experience surveys. An REH must submit quality measure data to the Secretary with respect to each year beginning in 2023 (or each year beginning on or after the date that is one year after one or more measures are first specified), and the Secretary is required to establish procedures to make the data available to the public on the CMS website. As discussed further in the CY 2023 OPPS/ASC proposed rule (87 FR 44755), CMS requested information on certain quality measures and quality reporting requirements for REHs.

More specifically, section 1861(kkk)(7)(B)(i) of the Act provides that, with respect to each year beginning with 2023 (or each year beginning on or after the date that is 1 year after one or more measures are first specified under subparagraph (C)), a REH shall submit data to the Secretary in accordance with clause (ii). Clause (ii) states that, with respect to each such year, a REH shall submit to the Secretary data in a form and manner, and at a time, specified by the Secretary for purposes of this subparagraph. For example, in the CY 2023 OPPS/ASC final rule, we finalized foundational administrative requirements for REHs participating in the REHQR Program (87 FR 71752, and 72149 through 72150).

# REHQR Program Quality Measures

The number of hospitals that convert to an REH and their characteristics may inform the selection of quality measures as we seek measures that are useable by REHs and that have sufficient volume of services to have meaningful measurement for individual facilities and, importantly, the public. CMS seeks to adopt a concise set of important, impactful, reliable, accurate, and clinically relevant measures for REHs that would inform consumer decision- making regarding care and drive further quality improvement efforts in the REH setting (87 FR 72137 through 72143). As we considered potential measures for the REHQR Program, we prioritized incorporating consensus-based entity (CBE) endorsed measures that reflect the most important areas of service for REH providers, aligning with best practices among other payers as well as adhering to CMS National Quality Strategy goals, HHS’ Strategic Plan and Initiatives, and the CMS Strategic Plan. When identifying measures for the REHQR Program, we focused on considerations such as care accountability and quality, rural relevance, low service and patient volume relative to the usefulness and reliability of these measures, and health equity.

We recognize REHs will be smaller hospitals that have limited resources compared with larger hospitals in metropolitan areas. For the REHQR Program, we intend to seek balance between the costs associated with reporting data and the benefits of ensuring safety and quality of care through measurement and public reporting. In assessing the collection of information burden associated with potential measures, we considered difficulties REHs may face when reporting measure data. Because REHs will consist of health care providers formerly operating as either CAHs or subsection (d) hospitals, we analyzed whether the current institutions have successfully reported these measures with sufficient volume to meet CMS case number thresholds for data to be publicly reported. We also considered whether measures selected for inclusion effectively account for the challenges of providing care that are specific to rural providers.

The REHQR Program has proposed to collect and publicly report data on quality-of-care measures for the REH setting. Measure data proposed could be submitted via one of two modes:

(1) chart-abstracted; and (2) claims-based, as seen in Table 1.

For measure data submitted as “chart-abstracted,” information is derived through analysis of a patient’s medical record. Chart-abstracted data involves manual data entry effort and requires additional effort or burden from hospitals.

For measure data submitted as “claims-based,” information is derived through analysis of administrative Medicare claims data and do not require additional effort or burden from hospitals.

# Table 1. Proposed REHQR Program Measures for the CY 2024 Reporting Period

|  |  |
| --- | --- |
| **Measure Name** | **CBE**  **No.** |
| **Chart-Abstracted Measures** | |
| Median Time for Discharged ED Patients (Previously referred to as Median Time from ED Arrival to ED Departure for Discharged ED Patients) | 0496 |
| **Claims-Based Measures** | |
| Abdomen Computed Tomography - Use of Contrast Material | 0514 |

|  |  |
| --- | --- |
| **Measure Name** | **CBE**  **No.** |
| Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy | 0669 |
| Hospital Visits after Hospital Outpatient Surgery | 3490 |

In the CY 2024 OPPS/ASC proposed rule, we are proposing to adopt four new measures, beginning with the CY 2024 reporting period, one which is chart-abstracted, and three which are claims-based.

The chart-abstracted measure is the Median Time from Emergency Department (ED) Arrival to ED Departure for Discharged ED Patients (Median Time for Discharged ED Patients) measure.

The claims-based measures include: (1) the Abdomen Computed Tomography (CT) - Use of Contrast Material (Abdomen CT) measure; (2) the Facility 7-Day Risk-Standardized Hospital Visit Rate After Outpatient Colonoscopy (7-Day Hospital Visit Rate After Outpatient Colonoscopy) measure; and (3) the Risk-Standardized Hospital Visits Within 7 Days After Hospital Outpatient Surgery (7-Day Hospital Visit Rate After Outpatient Surgery) measure.

# REHQR Program Forms

To administer the REHQR Program, one form is proposed for use: the Extraordinary Circumstances Exception (ECE) Request. In the event of extraordinary circumstances not within the control of the hospital, a hospital could request an exception from meeting program requirements. This form could be found online and be submitted electronically, by mail, or by fax. This form would not be completed on an annual basis; it would be on a need-to-use, exception basis and most hospitals will not need to complete this form in any given year. Thus, the burden for providers associated with the ECE Request form utilized in the REHQR Program is nominal, if any. We also note that the burden associated with completing and submitting an ECE request is accounted for in a separate PRA package, OMB Control Number 0938-1022 (expiration date January 31, 2026).[3](#_bookmark2)

More specifically, in the CY 2024 OPPS/ASC proposed rule, we are proposing to adopt and codify in 42 CFR 419.95(g) an ECE process which would allow REHs to request, and for CMS to grant, extensions or waivers with respect to the reporting of required quality data when there are extraordinary circumstances beyond the control of the REH, such as when either CMS or the facility experiences critical system errors that impact data collection or submission. This policy would align with other hospital quality reporting programs.

# Information Users

3 This burden is captured under another package because the hospital and ASC quality reporting and value-based purchasing programs use a single request form to avoid the use of multiple forms. Accounting for this burden under a single package ensures that all programs are using the same form, process, and burden estimates and avoids the risk of inconsistency or misalignment in CMS policies on this issue, as well as reducing inefficiencies in form updates and request processing.

As a quality reporting program, the REHQR Program will strive to have a streamlined measure set that provides meaningful measurement that also serves to differentiate facilities by quality of care while limiting burden to the fullest extent possible. The measure information collected will be made available to hospitals for their use in internal quality improvement initiatives, and, importantly, this information shall also be made available to Medicare beneficiaries, as well as to the general public, by providing hospital information on the *Care Compare* and the data.cms.gov website to assist them in making decisions about their healthcare.

Furthermore, under section 3014 of the Patient Protection and Affordable Care Act of 2010 (ACA), CMS is required to evaluate the impact and efficiency of CMS measures in quality reporting programs and to post the report every three years. As such, it is expected that the compilation of data from the REHQR Program and other CMS programs will be formally written into the next triennial National Impact Assessment Report.

# Use of Information Technology

To assist REHs in successfully abstracting and submitting data for chart-abstracted measures, CMS plans to employ the use of the established, free data collection tool, the CMS Abstraction and Reporting Tool (CART). CMS will also provide a secure data warehouse via the Hospital Quality Reporting (HQR) system for storage and transmittal of data as well as data validation and aggregation services prior to the release of data to the CMS *Care Compare* website.

Hospitals would have the option of using vendors to transmit the data, and CMS will engage a national support contractor to provide technical assistance with the data collection tool, other program requirements, and to provide education to support REHQR Program participants.

As reflected by the proposed collection and reporting of claims-based quality measures, efforts are being made to reduce burden by limiting the adoption of measures requiring the submission of patient-level information that must be acquired through chart-abstraction. In addition, proposed measures originate from the pre-existing and familiar Hospital Outpatient Quality Reporting (OQR) Program measure set and would use existing data and data collection systems.

# Duplication of Efforts

The information to be collected is not duplicative of similar information collected by CMS or other efforts to collect quality of care data for REH care. As required by statute, CMS requires REHs to submit quality measure data for services provided in the REH setting.

# Small Business

Information collection requirements are designed to allow maximum flexibility while also taking into consideration the burden associated with these requirements, specifically to REHs that must participate in REHQR Program quality reporting. This effort will also assist REHs in gathering information for their own quality improvement efforts.

# Less Frequent Collection

CMS has designed the collection of quality-of-care data to be the minimum necessary for data validation and calculation of summary figures to be reliable estimates of hospital performance. Under the initial proposed REHQR Program measure set, REHs would be required to submit one chart-abstracted measure to CMS on a quarterly basis. In addition, claims-based measures are calculated from Medicare FFS claims data; hospitals submit claims for reimbursement or payment per claims processing timeliness requirements. As such, if our proposals are finalized, data would be collected on three claims-based measures for participating REHs for services with encounter dates on or after January 1, 2024, for a 12-month or 36-month period, depending on the measure. To collect the information less frequently would compromise the timeliness of any calculated estimates.

# Special Circumstances

There are no special circumstances for the REHQR Program.

# Federal Register Notice/Outside Consultation

The 60-day Federal Register notice for this data collection was published on July 31, 2023 (88 FR 49552).

Measures adopted for the REHQR Program are required by statute to undergo a recognized consensus process. Section 3014 of the ACA modified section 1890(b) of the Act to require CMS to develop quality and efficiency measures through a “consensus-based entity.” To fulfill this requirement, the Measure Applications Partnership (MAP) was formed to review measures consistent with this provision of the Act. Beginning in CY 2023, the MAP will continue under a new name - the Partnership for Quality Measurement (PQM) - and will provide input on the Measures under Consideration (MUC) list as part of the Pre-Rulemaking Measure Review (PRMR). We refer readers to <https://p4qm.org/PRMR-MSR> for more information on the PRMR process.

CMS is additionally supported in this program’s efforts by organizations such as the Health Resources and Services Administration (HRSA), which provide CMS technical assistance in developing and/or identifying quality measures, and assisting in making collected information accessible, understandable, and relevant to the public. CMS also regularly engages interested parties (e.g. solicitation of comments).

# Payment/Gift to Respondent

The statutory authority for the REHQR Program does not require the Secretary to provide incentives for submitting quality measure data under the REHQR Program, nor does it require the Secretary to impose penalties for failing to comply with quality reporting program requirements under the REHQR Program. No other payments or gifts will be given to hospitals for participation.

# Confidentiality

All information collected under the REHQR Program will be maintained in strict accordance with statutes and regulations governing confidentiality requirements for CMS data, including the Privacy Act of 1974 (5 U.S.C. 552a), the Health Insurance Portability and Accountability Act (HIPAA), and the Quality Improvement Organizations confidentiality requirements, which can be found at 42 CFR Part 480. Data related to the REHQR Program would be housed in the HQR application group. HQR is a General Support System (GSS) housing protected health information (PHI). Users who access the HQR system are identity-managed to permit access to the system and have role-based restrictions (including log-in and password) to the data they can see. The System of Records Notice (SORN) in use for the quality programs including the REHQR Program is MBD 09-70-0536.

# Sensitive Questions

Case-specific clinical data elements would be collected and are necessary to calculate statistical measures. These statistical measures are the basis of subsequent improvement activities and cannot be calculated without the case specific data. Case-specific data would not be released to the public and are not releasable by requests under the Freedom of Information Act. Only hospital-specific data would be made publicly available as mandated by statute. In addition, the tools used for transmission of data are considered confidential forms of communication and are HIPAA-compliant.

# Burden Estimate (Total Hours & Wages)

* + 1. **Background**

In the CY 2024 OPPS/ASC proposed rule, we are proposing to adopt four new measures, beginning with the CY 2024 reporting period: (1) the Abdomen CT - Use of Contrast Material (Abdomen CT) measure; (2) the Median Time from ED Arrival to ED Departure for Discharged ED Patients (Median Time for Discharged ED Patients) measure; (3) the Facility 7-Day Risk- Standardized Hospital Visit Rate After Outpatient Colonoscopy (7-Day Hospital Visit Rate After Outpatient Colonoscopy) measure; and (4) the Risk-Standardized Hospital Visits Within 7 Days After Hospital Outpatient Surgery (7-Day Hospital Visit Rate After Outpatient Surgery) measure.

# Burden for the CY 2024 Reporting Period

For the REHQR Program, the burden associated with meeting program requirements includes the time and effort associated with collecting and reporting data on the required measures under the REHQR Program.

Based on our analysis of CAHs and subsection (d) hospitals, we have identified a maximum number of 746 hospitals which would be both eligible to transition to REH status and are located in a state where legislation has passed enabling transition to occur as of March 2023. For purposes of estimating burden, we assume that all 746 hospitals would submit data as part of the

REHQR Program during the CY 2024 reporting period. We will revise this estimate in future rules when updated data are available.

We estimate that collecting and reporting data required under the REHQR Program can be accomplished by staff with a median hourly wage of $52.12 per hour in accordance with the Bureau of Labor Statistics (BLS), based upon the median wage for Medical Records Specialists working in “general medical and surgical hospitals” which is $26.06 per hour before inclusion of overhead and fringe benefits. BLS describes Medical Records Specialists as those who “compile, process, and maintain medical records of hospital and clinic patients in a manner consistent with medical, administrative, ethical, legal, and regulatory requirements of the healthcare system”; therefore, we believe it is reasonable to assume that these individuals would be tasked with abstracting clinical data for submission for the REHQR 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 ($26.06 x 2 = $52.12) to estimate total cost is a reasonably accurate estimation method. Accordingly, we will use an hourly labor cost estimate of $52.12 ($26.06 salary plus $26.06 fringe and overhead) for calculation of burden forthwith.

# Chart-Abstracted Measures Burden

In the CY 2024 OPPS/ASC proposed rule, we are proposing to adopt the Median Time from ED Arrival to ED Departure for Discharged ED Patients measure beginning with the CY 2024 reporting period. This chart-abstracted measure was previously adopted as part of the Hospital OQR Program in the CY 2011 OPPS/ASC final rule with comment period (75 FR 72086).

Similar to reporting of this measure to the Hospital OQR Program as currently approved under OMB control number 0938-1109 (expiration date February 28, 2025), we assume that for chart- abstracted measures where patient-level data are submitted directly to CMS, we estimate it would take 2.9 minutes, or 0.049 hours, per case per measure to collect and submit the data for each submitted case. Further, based on sample size requirements for the similar measure in the Hospital OQR Program, we assume that each REH would abstract and submit data from 63 cases per quarter, for a total of 252 cases per year. Therefore, we estimate that it would take approximately 12.2 hours (0.049 hours x 252 cases) at a cost of approximately $636 per hospital (12.2 hours x $52.12/hour) to collect and report data for this measure. Therefore, for all participating REHs, we estimate an annual chart-abstraction burden of 9,101 hours (12.2 hours per REH x 746 REHs) at a cost of $474,344 (9,101 hours x $52.12/hour).

# Claims-Based Measures Burden

In the CY 2024 OPPS/ASC proposed rule, we are proposing to adopt the following claims-based measures beginning with the CY 2024 reporting period: (1) the Abdomen CT measure; (2) the 7- Day Hospital Visit Rate After Outpatient Colonoscopy measure; and (3) the 7-Day Hospital Visit Rate After Outpatient Surgery measure.

Claims-based measures are derived through analysis of administrative claims data and do not require additional information collection burden on behalf of hospitals. As a result, adoption of these measures would not result in additional burden for hospitals participating in the REHQR Program.

# Total Burden for the CY 2024 Reporting Period and Subsequent Years

Based on the preceding discussion, Table 2 below summarizes our calculations of burden for the CY 2024 reporting period and subsequent years.

# Table 2. Proposed Total Burden for the CY 2024 Reporting Period and Subsequent Years

|  |  |  |
| --- | --- | --- |
|  | **Total Hours** | **Total Cost** |
| Chart-Abstracted Measures | 9,101 | $474,344 |
| Claims-Based Measures | N/A | N/A |
| **Total** | **9,101** | **$474,344** |

The estimated annual burden for the CY 2024 reporting period is 9,101 hours at a cost of

$474,344.

# Capital Costs (Maintenance of Capital Costs)

There are no capital costs being placed on the REHs. In fact, successful submission would result in a REH meeting REHQR Program requirements, while having to expend no capital costs for participation. CMS is providing a data collection tool and method for submission of data to the participants. There are no additional data submission requirements placing additional cost burdens on REHs.

# Cost to Federal Government

The cost to the Federal Government for maintaining program activities is for Federal staff, supporting data system architecture, data storage, maintenance and updating of information technology infrastructure on the HQR system secure portal, providing ongoing technical assistance to hospital and data vendors, calculation of claims-based measures, measure development and maintenance, the provision of hospitals with feedback and preview reports, as well as costs associated with public reporting. These costs are estimated to be $10,050,000 annually. Additionally, this program takes one CMS staff at a GS-13 Step 5 level to operate. GS- 13 Step 5 approximate annual salary is $126,949 plus benefits (30%) of $38,085 for a total of

$168,034.

For proposed claims-based measures, the cost to the Federal Government is minimal. CMS uses data from the CMS National Claims History system that are already being collected for provider reimbursement; therefore, no additional data would need to be submitted by hospitals for claims- based measures.

The total annual estimated cost to the Federal Government is $10,545,101.

# Program or Burden Changes

This is a new information collection request. We are requesting initial approval of annual information collection burden of 9,101 hours at a cost of $474,344 for the REHQR Program beginning with the CY 2024 reporting period.

# Publication

The goal of the data collection is to tabulate and publish hospital specific data. CMS would display information on the quality of care provided in the REH setting for public viewing as required by CAA 2021. We anticipate updating these data on at least an annual basis.

# Expiration Date

CMS will display the expiration date on the collection instruments.

# Certification Statement

There are no exceptions to the certification statement.