A. Background

This is a request for a new information collection request related to the special requirements for Rural Emergency Hospitals (REHs) and is associated with a final rule titled "*Medicare Program*; *Proposed Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Policy Changes and Fiscal Year 2024 Rates; Quality Programs and Medicare Promoting Interoperability Program Requirements for Eligible Hospitals and Critical Access Hospitals; Rural Emergency Hospital and Physician Owned Hospital Requirements; and Provider and Supplier Disclosure of Ownership*" (88 FR TBD). This final rule went on display on the Federal Register website on August 1, 2023, and is scheduled for publication on August 28, 2023. The section of the final rule titled **Special Requirements for Rural Emergency Hospitals (REHs)** begins on page 1674 of the display copy.¹

This ICR involves the time and cost required for an eligible facility, applying for enrollment as a Rural Emergency Hospital (REH), to gather, to prepare and submit the additional information required to be submitted with its application for enrollment as an REH. There are no forms associated with this ICR.

Section 125 of the CAA,² which added section 1861(kkk) to the Social Security Act (the Act), sets forth the statutory authority for Rural Emergency Hospitals (REHs) as a new Medicare provider, effective January 1, 2023.

As per section 1861kkk(a)(3) of the Act, the following facilities that were enrolled and certified to participate in Medicare as of December 27, 2020, are eligible to be an REH:

- 1. Critical Access Hospitals (CAHs); and
- 2A. 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) (referred to as rural hospital); or
- 2B. A subsection (d) hospital (as so defined) with not more than 50 beds that was treated as being located in a rural area pursuant to section 1886(d)(8)(E) of the Act (referred to as rural hospital); and
- 3. Facilities that were enrolled as CAHs or rural hospitals with not more than 50 beds as of December 27, 2020, and then subsequently closed after that date, would also be eligible to seek REH designation if they re-enroll in Medicare and meet all the CoPs and requirements for REHs.

¹ This is the actual page count number because the official Federal Register volume and page numbers are not shown on the display copy of the final rule.

² <u>https://www.congress.gov/bill/116th-congress/house-bill/133/text</u>

Sections 1861(kkk)(4)(A)(i) through (iv) of the Act require that an eligible facility that submits an application for enrollment as an REH under section 1866(j) of the Act, must also submit additional information that must include an action plan containing: (1) a plan for initiating REH services (which must include the provision of emergency department services and observation care); (2) a detailed transition plan that lists the specific services that the provider will retain, modify, add, and discontinue as an REH; (3) a detailed description of other outpatient medical and health services that it intends to furnish on an outpatient basis as an REH; and (4) information regarding how the provider intends to use the additional facility payment provided under section 1834(x)(2) of the Act, including a description of the services that the additional facility payment would be supporting, such as the operation and maintenance of the facility and the furnishing of covered services (for example, telehealth services and ambulance services).

As with all other providers and suppliers, REHs are required to be enrolled in Medicare to receive payments for services and items furnished to Medicare beneficiaries. The REH enrollment regulations at 42 CFR § 424.575 state that eligible facilities must submit a CMS 855A change of information application (OMB control number 0938-0685), rather than an initial enrollment application, to enroll as an REH. The prospective REH facility must submit this application to their designated Medicare Administrative Contractor (MAC).

The additional information is submitted to the State Survey Agency (SA) at the same time the CMS-855A application is sent to the MAC. Once reviewed by the SA, the CMS location reviews the information and makes a final determination for certification of the REH. Facilities may submit this information on facility letterhead or may use a template provided in <u>QSO Memo 23-07</u>, titled "*Guidance for Rural Emergency Hospital Provisions, Conversion Process and Conditions of Participation*."

In this final rule, we finalized new regulations at 42 CFR § 488.70, titled *Special Requirements for Rural Emergency Hospitals*, which codify the statutory requirement that eligible facilities that submit an application for enrollment as an REH under section 1866(j) of the Act must also submit additional information and what that information must be.

Also, through this final rule, we have finalized updates to certain definitions in the survey and certification regulations to include REHs as a provider type. Specifically, we finalized updates to the definition of *"Provider of services or provider"* at 42 CFR 488.1 to include REHs and have added REHs to the other applicable regulations including *"Statutory basis"* at §488.2; *"Documentation of findings"* at §488.18; and *"Requirements for providers"* at §489.102.

B. Justification

1. <u>Need & Legal Basis</u>

In response to rural hospital closures, and to work toward addressing barriers in access to health care for rural communities, the Consolidated Appropriations Act (CAA) of 2021 was

signed into law on December 27, 2020. Section 125 of the CAA added section 1861(kkk) to the Social Security Act (the Act). This statute establishes and sets forth the statutory authority for Rural Emergency Hospitals (REHs) as a new Medicare provider, effective January 1, 2023. This new provider type will promote equity in health care for those living in rural communities by facilitating access to needed services.

On the November 23, 2022, we published a final rule titled "Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Organ Acquisition; Rural Emergency Hospitals: Payment Policies, Conditions of Participation, Provider Enrollment, Physician Self-Referral; New Service Category for Hospital Outpatient Department Prior Authorization Process; Overall Hospital Quality Star Rating; COVID–19" (87 FR 71748).³ This rule finalized the Conditions of Participation (CoPs) that REHs must meet in order to participate in the Medicare and Medicaid programs as well as REH payment policies, quality measures, initial reporting requirements, and enrollment policies.

On January 26, 2023, CMS released QSO–23–07–REH⁴, which provided information about the additional information requirements specified by section 1861(kkk)(4)(A)(i)– (iv) of the Act as well as guidance regarding the process by which eligible facilities must submit the additional information.

In the above-referenced August 1, 2023, final rule (that is the subject of this PRA package), we finalized regulations which codify the additional information requirements. We also finalized updates to certain definitions in the survey and certification regulations to include REHs as a provider. Specifically, we updated the definition of *"Provider of services or provider"* at 42 CFR 488.1 to include REHs and have added REHs to the other applicable regulations including *"Statutory basis"* at §488.2; *"Documentation of findings"* at §488.18; and *"Requirements for providers"* at §489.102.

2. Information Users

CMS would be the user of any information that is collected because of the requirements imposed under the new or revised regulations. CMS will use this information to determine a facility's compliance with the statutory requirements for REHs during the initial enrollment and conversion process of an eligible facility. Additionally, as set forth at 1861(kkk)(2)(A), the additional information will be made available to the public in a form and manner determined appropriate by the Secretary.

Currently, CMS is in the process of developing the functionality for publicly posting the additional information on the CMS website. We plan to release a QSO memo announcing this information when the process is complete.

3. <u>Improved Information Technology</u>

³ See: https://www.federalregister.gov/d/2022-23918).

⁴ <u>https://www.cms.gov/files/document/qso-23-07-reh.pdf</u>

Prospective REH facilities would be required to submit the required application and additional information to CMS by email.

4. Duplication of Similar Information

There is no duplication of information required by the proposed new or revised regulations because the prospective new REH facilities are not required to provide this information to any other persons or agencies.

5. Small Business

The providers that would apply to be an REH would mostly be small businesses. We would minimize the impact of the data reporting requirements to small businesses by allowing this data to be reported by email instead of requiring the use of a special computer program or requiring the REH to make hard copies of the information and sending via U.S. mail.

6. Less Frequent Collection

Facilities that want to convert to an REH will only need to submit the required information once. This is a one-time burden to these facilities.

7. Special Circumstances for Information Collection

This is a one-time data submission requirement.

8. Federal Register and Outside Consultation

The proposed IPPS rule for Acute Care Hospitals and LTCH Prospective Payment System and Policy Changes and FY 2024 was published on May 1, 2023 (88 FR 26658).

The final rule (88 FR TBD) will serve as the 30-day PRA notice.

- The final rule went on display on the Federal Register website on August 1, 2023⁵.
- The final rule published on August 28, 2023 (88 FR 58640).

9. Payments or Gifts

⁵ See: <u>https://public-inspection.federalregister.gov/2023-16252.pdf</u>

There are no payments or gifts associated with this collection.

10. <u>Confidentiality</u>

No confidential or personally identifiable patient information will be collected. In accordance with section 1861(kkk)(2)(A) of the Act, action plans will be available to the public and will eventually be posted on the CMS website.

11. Sensitive Questions

There are no questions of a sensitive nature.

12. Estimate of Burden

In the final rule, we finalized new regulations that will require that an eligible facility submit an application for enrollment as an REH under section 1866(j) of the Act. These new regulations will also require a prospective REH also submit additional information to include an action plan containing: (1) a plan for initiating REH services (as those services are defined in 42 CFR 485.502, and which must include the provision of emergency department services and observation care); (2) a detailed transition plan that lists the specific services that the provider will retain, modify, add, and discontinue as an REH; (3) a detailed description of other outpatient medical and health services that it intends to furnish on an outpatient basis as an REH; and (4) information regarding how the provider intends to use the additional facility payment provided under section 1834(x)(2) of the Act, including a description of the services that the additional facility payment would be supporting, such as the operation and maintenance of the facility and the furnishing of covered services (for example, telehealth services and ambulance services).

We estimate that in 2023, approximately 68 eligible facilities (that is, CAHs and small rural hospitals with not more than 50 beds) will elect to convert to REHs. Thereafter, we estimate that there will be approximately 8 eligible facility per year that would convert to an REH.

a. <u>Time Burden Associated with the Special Requirements for REHs:</u>

We estimate that it would take *each* CAH or small rural hospital **4 hours** to prepare this action plan containing the four required elements specified above.

We further estimate that the annual time burden *across all* 68 facilities that would convert to an REH would be **272 hours**.

- 4 hours × 68 facilities = 272 hours
- b. <u>Cost Burdens Associated with the Special Requirements for REHs:</u>

We believe that the person at the facility who would perform this task would be the hospital administrator or CEO. This person would fall under the U.S. Bureau of Labor Statistics job category of Medical and Health Services Manager. According to the U.S. Bureau of Labor Statistics, the mean hourly wage for a Medical and Health Services Manager is \$57.61. This wage, adjusted for the employer's fringe benefits and overhead would be **\$115**⁶.

We estimate that the cost burden to *each* eligible facility for preparing the action plan containing the four required elements would be **\$460.**

• 4 hours \times \$115 = \$460

We further estimate that the cost burden *across all 68* eligible CAHs and small rural hospitals converting to REHs would be **\$31,280**.

• 272 hours × \$115 per hour = \$31,280

It is important to note that this is a one-time burden to the facility. After this task has been completed, this burden will be non-recurring.

c. <u>Summary of Burden:</u>

Time Burden <mark>Per Each</mark> Provider	
Name of Task	Time Burden
Time burden for preparation of each action plan & additional information	4 hours
TOTAL	4 hours

Time Burden Across All REH Providers		
Name of Task	Time Burden	
Total annual time burden <i>across all</i> prospective REHs for preparation of all action plan & additional information– in 2023	272 hours	
TOTAL	272 hours	
Cost Burden <mark>Per Each</mark> Provider		
Name of Task	Cost Burden	

⁶ For the adjusted hourly wage rate, we doubled the mean hourly wage to cover overhead and fringe benefits, according to standard HHS estimating procedures. If the total cost after doubling resulted in 0.50 or more, the cost was rounded up to the next dollar. If it was 0.49 or below, the total cost was rounded down to the next dollar.

Cost burden for preparation of <i>each</i> action plan & additional information	\$460
TOTAL	\$460

Cost Burden Across All REH Providers		
Name of Task	Cost Burden	
Total annual cost burden <i>across all</i> prospective REHs for preparation of all action plan & additional information	\$31,280	
TOTAL	\$31,280	

13. Capital Costs

There are no anticipated capital costs associated with this collection.

14. Federal Cost Estimates

Once complete, the SA will forward the additional information to the CMS location, along with a recommendation for certification or denial. The CMS location is responsible for making the final determination for certification of the REH.

We estimate that it would take a CMS reviewer **1 hour** to review each REH application. We further estimate that the total annual time expended by CMS reviewers for this task would be **68 hours**.

• 1 hour x 68 REHs = 68 hours

We believe that the person at CMS who would perform this task would have the job title of "Reviewer." We further believe that this person would be a GS-13, step 5. Such a person in the Pennsylvania region would have an annual salary of \$116,459, and which equates to an average hourly pay of **\$55.99**.⁷

We estimate that the cost associated with review of *each* REH application would be \$55.99.

• 1 hour x \$55.99 per hour = \$55.99

⁷ https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2022/PHL_h.pdf

We further estimate that the cost for the review of *all* REH applications submitted per year would be **\$3,807**.

• 68 hours x \$55.99 hours = \$3,807

15. <u>Burden Changes/Program Changes</u>

This is a new information collection.

16. Publication and Tabulation Dates

The results of this collection will not be published.

17. OMB Expiration Date

CMS will display the expiration date on QSOG webpage on the CMS.gov website.

18. <u>Certification Statement</u>

There is no exception to this statement.