

Improvement Organization (QIO) and how to file a request. For all Medicare beneficiaries, hospitals must deliver valid, written notice of a beneficiary's rights as a hospital inpatient, including discharge appeal rights. The hospital must use a standardized notice, as specified by CMS. This is satisfied by IM delivery.

Consistent with 42 CFR 405.1205 for Original Medicare and 422.620 for Medicare health plans, hospitals must provide the initial IM within 2 calendar days of admission. A follow-up copy of the signed IM is given no more than 2 calendar days before discharge. The follow-up copy is not required if the first IM is provided within 2 calendar days of discharge. In accordance with 42 CFR 405.1206 for Original Medicare and 422.622 for Medicare health plans, if a beneficiary/enrollee appeals the discharge decision, the beneficiary/enrollee and the QIO must receive a detailed explanation of the reasons services should end. This detailed explanation is provided to the beneficiary/enrollee using the DND, the second notice included in this renewal package. *Form Number:* CMS-10065/10066 (OMB control number: 0938-1019); *Frequency:* Yearly; *Affected Public:* Private Sector (Business or other for-profits, Not-for-Profit Institutions); *Number of Respondents:* 14,087,086; *Total Annual Responses:* 14,087,086; *Total Annual Hours:* 2,385,107. (For policy questions regarding this collection contact Janet Miller at [Janet.Miller@cms.hhs.gov](mailto:Janet.Miller@cms.hhs.gov)).

2. *Type of Information Collection Request:* Extension without change of a currently approved collection; *Title of Information Collection:* Medicare Outpatient Observation Notice (MOON); *Use:* The Medicare Outpatient Observation Notice (MOON) serves as the written notice component of this mandatory notification process. The standardized content of the MOON includes all informational elements required by statute, in language understandable to beneficiaries, and fulfills the regulatory requirements at 42 CFR part 489.20(y).

The MOON is a standardized notice delivered to persons entitled to Medicare benefits under Title XVIII of the Act who receive more than 24 hours of observation services, informing them that their hospital stay is outpatient and not inpatient, and the implications of being an outpatient. This information collection applies to beneficiaries in Original Medicare and enrollees in Medicare health plans. *Form Number:* CMS-10611 (OMB control number: 0938-1308); *Frequency:* Yearly; *Affected Public:* State, Local, or Tribal

Governments; *Number of Respondents:* 4,312; *Total Annual Responses:* 683,222; *Total Annual Hours:* 170,806. (For policy questions regarding this collection contact Janet Miller at [Janet.Miller@cms.hhs.gov](mailto:Janet.Miller@cms.hhs.gov)).

Dated: August 18, 2022.

**William N. Parham, III,**  
*Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

[Document Identifiers: CMS-10668, CMS-10455 and CMS-10430]

#### Agency Information Collection Activities: Submission for OMB Review; Comment Request

**AGENCY:** Centers for Medicare & Medicaid Services, Health and Human Services (HHS).

**ACTION:** Notice.

**SUMMARY:** The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, and to allow a second opportunity for public comment on the notice. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

**DATES:** Comments on the collection(s) of information must be received by the OMB desk officer by September 23, 2022.

**ADDRESSES:** Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this

notice to [www.reginfo.gov/public/do/PRAMain](http://www.reginfo.gov/public/do/PRAMain). Find this particular information collection by selecting "Currently under 30-day Review—Open for Public Comments" or by using the search function.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' website address at: <https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing>.

**FOR FURTHER INFORMATION CONTACT:** William Parham at (410) 786-4669.

**SUPPLEMENTARY INFORMATION:** Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term "collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires federal agencies to publish a 30-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice that summarizes the following proposed collection(s) of information for public comment:

1. *Type of Information Collection Request:* Revision of a currently approved collection; Quality Measures and Administrative Procedures for the Hospital-Acquired Condition Reduction Program; *Use:* The Centers for Medicare & Medicaid Services (CMS) is committed to promoting higher quality healthcare and improving outcomes for Medicare beneficiaries. The Hospital-Acquired Condition (HAC) Reduction Program is established by section 1886(p) of the Social Security Act, as added by Section 3008 of the Affordable Care Act (Pub. L. 111-148), and requires the Secretary to reduce payments to subsection (d) hospitals in the worst-performing quartile of all subsection (d) hospitals by 1 percent effective beginning on October 1, 2014 and subsequent years. For the FY 2025 program year we are proposing in the Fiscal Year (FY) 2023 Inpatient Prospective Payment System (IPPS)/

Long-Term Care Hospital (LTCH) PPS proposed rule to suppress all six measures in the HAC Reduction Program and not calculate measure scores or Total HAC Scores for any hospital such that no hospital will receive a payment reduction due to the significant impacts of the COVID-19 pandemic on the quality measures. We are not proposing any policies in the FY 2023 IPPS/LTCH PPS proposed rule which result in a change to our estimated burden. To administer its requirements, the HAC Reduction Program relies on data collection established through the Centers for Disease Control and Prevention's (CDC) OMB control number, 0920-0666, and validation processes established through the Hospital Inpatient Quality Reporting (IQR) Program's OMB control number, 0938-1022. However, in the FY 2019 IPPS/LTCH PPS final rule, the Hospital IQR Program finalized the removal of the CDC National Healthcare Safety Network (NHSN) Healthcare-associated Infection (HAI) measures and NHSN HAI validation processes beginning on January 1, 2020. To continue validation of these measures, the HAC Reduction Program adopted validation templates similar to the ones previously used under the Hospital IQR Program. These templates continue the HAC Reduction Program's use and validation of NHSN HAI data.

The HAC Reduction Program identifies the worst-performing quartile of hospitals by calculating a Total HAC Score derived from the CMS Patient Safety and Adverse Events Composite (CMS PSI 90) and NHSN HAI measures, which require that we collect claims-based and chart-abstracted measures data, respectively. The HAC Reduction Program validates NHSN HAI data reported by subsection (d) hospitals to ensure that hospitals report correct NHSN HAI measure data, and the Total HAC Score is calculated using accurate data. The HAC Reduction Program may penalize any hospitals that fail validation by assigning the maximum Winsorized z-score for the set of measures that fail validation, for use in the Total HAC Score calculation. The collection of information for validation is necessary to ensure that the HAC Reduction Program and Total HAC Score are administered fairly.

The HAC Reduction Program will continue to receive NHSN HAI data for hospitals from CDC. Because the burden associated with submitting data for the HAI measures (CDI, CAUTI, CLABSI, MRSA, and SSI) is captured under a separate OMB control number, 0920-0666, we do not provide an independent estimate of the burden associated with

collecting data for these measures for the HAC Reduction Program. We also do not provide an estimate of burden for the claims-based PSI 90 measure, because this measure is collected using Medicare FFS claims that hospitals are already submitting to the Medicare program for payment purposes. We also do not provide an estimate of burden for validation of data submitted for the PSI 90 measure, because Medicare claims are audited under the Medicare Fee for Service (FFS) Recovery Audit Program. *Form Number:* CMS-10668 (OMB control number: 0938-1352); *Frequency:* Yearly; *Affected Public:* Private Sector (Business or other for-profit and Not-for-profit institutions), Federal Government, and State, Local or Tribal Governments; *Number of Respondents:* 400; *Total Annual Responses:* 400; *Total Annual Hours:* 28,800. (For policy questions regarding this collection contact Jennifer Tate at 410-786-0428).

*2. Type of Information Collection Request:* Reinstatement with change of a previously approved collection; *Title of Information Collection:* Report of a Hospital Death Associated with Restraint or Seclusion; *Use:* Provisions implementing this statutory reporting requirement for hospitals participating in Medicare are found at 42 CFR 482.13(g), as revised in the final rule that published on May 16, 2012 (77 FR 29034). This regulation also applies to Critical Access Hospitals (CAHs) with distinct part units (DPUs); since CAH DPUs are subject to the Hospital Conditions of Participation. The regulation at 42 CFR 482.13(g) requires that hospitals and CAHs with DPUs report deaths associated with the use of restraint and/or seclusion directly to the CMS locations. This regulation requires that information about patient deaths associated with the use of restraint and/or seclusion must be reported to the CMS Locations using the online CMS-10455 form titled "*Report Of A Hospital Death Associated With The Use Of Restraint Or Seclusion.*"

When a death occurs in a hospital (including Critical Access Hospital (CAH) with a rehabilitation or psychiatric Distinct Part Unit (DPU)) that is associated with the use of restraints and/or seclusion, the hospital staff must complete the online Form CMS-10455 (42 CFR 482.13(g)(1)). The hospital staff must also document the date and time that CMS was notified of the death in the patient's medical record (42 CFR 482.13(g)(3)(i)).

When a death occurs during the use of 2-point soft cloth wrist restraints with no seclusion, or within 24 hours after the patient was removed from such restraints, the hospital must document

the information required by 42 CFR 482.13(g)(4)(ii) into a hospital log or internal system within 7 days from the date of death (42 CFR 482.13(g)(4)(i)). The hospital is not required to submit this log or internal records to the CMS Location, however, they must be made available in either written or electronic form to CMS immediately upon request (42 CFR 482.13(g)(4)(iii)). In addition, the hospital staff must also document the date and time that the required information was entered into the hospital's log or internal system in the patient's medical record (42 CFR 482.13(g)(3)(ii)). *Form Number:* CMS-10455 (OMB control number: 0938-1210); *Frequency:* Occasionally; *Affected Public:* Private Sector; *Number of Respondents:* 3,137; *Number of Responses:* 3,137; *Total Annual Hours:* 1,210. (For policy questions regarding this collection contact Caroline Gallaher at 410-786-8705.)

*3. Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Information Collection Requirements for Compliance with Individual and Group Market Reforms under Title XXVII of the Public Health Service Act; *Use:* Sections 2723 and 2761 of the Public Health Service Act (PHS Act) direct the Centers for Medicare and Medicaid Services (CMS) to enforce a provision (or provisions) of title XXVII of the PHS Act (including the implementing regulations in parts 144, 146, 147, and 148 of title 45 of the Code of Federal Regulations) with respect to health insurance issuers when a state has notified CMS that it has not enacted legislation to enforce or that it is not otherwise enforcing a provision (or provisions) of the group and individual market reforms with respect to health insurance issuers, or when CMS has determined that a state is not substantially enforcing one or more of those provisions. Section 2723 of the PHS Act directs CMS to enforce an applicable provision (or applicable provisions) of title XXVII of the PHS Act (including the implementing regulations in parts 146 and 147 of title 45 of the Code of Federal Regulations) with respect to group health plans that are non-Federal governmental plans. This collection of information includes requirements that are necessary for CMS to conduct compliance review activities. *Form Number:* CMS-10430 (OMB control number: 0938-0702); *Frequency:* Annually; *Affected Public:* Private Sector, State, Local, or Tribal Governments; *Number of Respondents:* 794; *Total Annual Responses:* 51,385; *Total Annual Hours:* 1,786. (For policy

questions regarding this collection contact Usree Bandyopadhyay at 410-786-6650).

Dated: August 19, 2022.

**William N. Parham, III,**

*Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

[Document Identifiers: CMS-10379]

#### Agency Information Collection Activities: Proposed Collection; Comment Request

**AGENCY:** Centers for Medicare & Medicaid Services, Health and Human Services (HHS).

**ACTION:** Notice.

**SUMMARY:** The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (the PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information (including each proposed extension or reinstatement of an existing collection of information) and to allow 60 days for public comment on the proposed action. Interested persons are invited to send comments regarding our burden estimates or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

**DATES:** Comments must be received by October 24, 2022.

**ADDRESSES:** When commenting, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in any one of the following ways:

1. *Electronically.* You may send your comments electronically to <http://www.regulations.gov>. Follow the instructions for "Comment or Submission" or "More Search Options"

to find the information collection document(s) that are accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number: \_\_\_\_\_, Room C4-26-05, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' website address at website address at <https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing>

**FOR FURTHER INFORMATION CONTACT:** William N. Parham at (410) 786-4669.

#### SUPPLEMENTARY INFORMATION:

##### Contents

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection's supporting statement and associated materials (see **ADDRESSES**).

##### CMS-10379—Rate Increase Disclosure and Review Reporting Requirements

Under the PRA (44 U.S.C. 3501-3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term "collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA requires federal agencies to publish a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice.

##### Information Collection

1. *Type of Information Collection Request:* Revision of a previously approved information collection; *Title of Information Collection:* Rate Increase Disclosure and Review Reporting Requirements; *Use:* 45 CFR part 154 implements the annual review of

unreasonable increases in premiums for health insurance coverage called for by section 2794. The regulation established a rate review program to ensure that all rate increases that meet or exceed an established threshold are reviewed by a state or the Centers for Medicare and Medicaid Services (CMS) to determine whether the rate increases are unreasonable. Accordingly, issuers offering non-grandfathered health insurance coverage in the individual and/or small group markets are required to submit Rate Filing Justifications to CMS. Section 154.103 exempts grandfathered health plan coverage as defined in 45 CFR 147.140, excepted benefits as described in section 2791(c) of the PHS Act and student health insurance coverage, as defined in § 147.145, from Federal rate review requirements.

The Rate Filing Justification consists of three parts. All issuers must continue to submit a Uniform Rate Review Template (URRT) (Part I of the Rate Filing Justification) for all single risk pool plans. Section 154.200(a)(1) establishes a 15 percent federal default threshold for reasonableness review. Issuers that submit a rate filing that includes a plan that meets or exceeds the threshold must include a written description justifying the rate increase, also known as the consumer justification narrative (Part II of the Rate Filing Justification). We note that the threshold set by CMS constitutes a minimum standard and most states currently employ stricter rate review standards and may continue to do so. Issuers offering a QHP or any single risk pool submission containing a rate increase of any size must continue to submit an actuarial memorandum (Part III of the Rate Filing Justification). *Form Number:* CMS-10379 (OMB control number: 0938-1141); *Frequency:* Annually; *Affected Public:* Private Sector; Businesses or other for-profits, Not-for-profit institutions; *Number of Respondents:* 626; *Total Annual Responses:* 820; *Total Annual Hours:* 17,788. (For policy questions regarding this collection contact Lisa Cuzzo at 410-786-1746.)

Dated: August 19, 2022.

**William N. Parham, III,**

*Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.*

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