



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier CMS-10611, CMS-R-282 and CMS-R-235]

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

AGENCY: Centers for Medicare & Medicaid 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 **[INSERT DATE 30 DAYS AFTER THE DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

ADDRESSES: When commenting on the proposed information collections, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be received by the OMB desk officer via one of the following transmissions:

OMB, Office of Information and Regulatory Affairs

Attention: CMS Desk Officer

Fax Number: (202) 395-5806 OR

E-mail: OIRA_submission@omb.eop.gov

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' Web Site address at Web Site address at

[https://www.cms.gov/Regulations-and-](https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html)

[Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html](https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html)

1. E-mail your request, including your address, phone number, OMB number, and CMS document identifier, to Paperwork@cms.hhs.gov.

2. Call the Reports Clearance Office at (410) 786-1326.

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:* Extension without change of a currently approved collection; *Title of Information Collection:* Medicare Outpatient Observation Notice (MOON); *Use:* On August 6, 2015, Congress enacted the Notice of Observation Treatment and Implication for Care Eligibility Act (NOTICE Act) Public Law 114-42, amending Section 1866(a)(1) of the Social Security Act (the Act) (42 U.S.C. 1395cc(a)(1)), by adding a new subparagraph (Y). The NOTICE Act requires hospitals and CAHs to provide written notification and oral explanation to individuals who receive observation services as outpatients for more than 24 hours.

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.

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 fulfils the regulatory requirements at 42 CFR Part 489.20(y).

The MOON is not given every time items and services are furnished in a hospital or CAH. Rather, hospitals are only required to deliver the MOON to individuals receiving observation services as outpatients for more than 24 hours. *Form Number:* CMS-10611 (OMB control number: 0938-1308); *Frequency:* Yearly; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 4,373; *Total Annual Responses:* 946,209; *Total Annual Hours:* 236,552. (For policy questions regarding this collection contact Janet Miller at Janet.Miller@cms.hhs.gov.)

2. *Type of Information Collection Request:* Revision with change of a currently approved collection; *Title of Information Collection:* Health Plan Appeals and Grievance Data Collection and Reporting Requirements, Data Disclosure Requirements under section 422.111; *Use:* Part 422 of Title 42 of the Code of Federal Regulations (CFR) distinguishes between certain information a Medicare Advantage (MA) organization must provide to each enrollee (on an annual basis) and information that the MA organization must disclose to any MA eligible individual (upon request). This requirement can be found in § 1852(c)(2)(C) of the Social Security Act and in 42 CFR § 422.111(c)(3) which states that MA organizations must disclose information pertaining to the number of disputes, and their disposition in the aggregate, with the categories of grievances and appeals, to any individual eligible to elect an MA organization who requests this information.

The appeals and grievance data form is an OMB approved form for use by Medicare Advantage organizations to disclose grievance and appeal data, upon request, to individuals eligible to elect an MA organization. By utilizing the form, MA organizations will meet the disclosure requirements set forth in regulations at 42 C.F.R. 422.111(c)(3).

In an effort to identify opportunities to reduce burden for this collection, we compared data provided by plans to CMS in Part C reporting requirements (OMB 0938-1054) with the requirements to provide aggregate grievance and appeals data to MA eligible beneficiaries. We found that data reported to CMS in the Part C reporting requirements was data that would meet the disclosure requirements at § 1852(c)(2)(C) of the Social Security Act and 42 CFR § 422.111(c).

We are proposing to revise this form by allowing plans to use data collected for Part C reporting requirements (OMB 0938-1054) that also meet requirements for this collection. This change merges and aligns the collection and reporting periods, so MA plans do not need to keep two separate sets of data and reports each year.

For CMS Part C reporting requirements, data is collected quarterly, but only reported annually. To match this and reduce plan burden, CMS is revising this form to use the data reported annually to CMS, and that data be valid for one year versus creating a new report every six months. Further, data provided to enrollees would be consistent with data provided to CMS. *Form Number: CMS-R-282 (OMB control number: 0938-0778); Frequency: Yearly; Affected Public: State, Local, or Tribal Governments; Number of Respondents: 733; Total Annual Responses: 59,133; Total Annual Hours: 5,405.* (For policy questions regarding this collection

contact Staci Paige at 410-786-2045.)

3. *Type of Information Collection Request:* Reinstatement with change of a currently approved collection; *Title of Information Collection:* Data Use Agreement (DUA) Form; *Use:* The Privacy Act of 1974 allows for discretionary releases of data maintained in Privacy Act protected systems of records under §552a(b) (Conditions of Disclosure). The mandate to account for disclosures of data under the Privacy Act is found at §552a(c)(Accounting of Certain Disclosures). This section states that certain information must be maintained regarding disclosures made by each agency. This information is: Date, Nature, Purpose, and Name/Address of Recipient. Section 552a(e) sets the overall Agency Requirements that each agency must meet in order to maintain records under the Privacy Act.

The Data Use Agreement (DUA) form is needed as part of the review of each CMS data request to ensure compliance with the requirements of the Privacy Act for disclosures that contain PII. The DUA form also provides data requestors and custodians with a formal means to agree to the data protection and destruction statutory and regulatory requirements of CMS' PII data.

When entities, such as academic, federal or state agency researchers or CMS contractors request CMS PII/PHI data, they enter into a Data Use Agreement (DUA) with CMS. The DUA stipulates that the recipient of CMS data must properly protect the data according to all applicable data security standards and also provide for its appropriate destruction at the completion of the project/study or the expiration date of the DUA. The DUA form enables the data recipient and CMS to document the request and approval for release of CMS data. *Form*

Number: CMS-R-235 (OMB control number: 0938-0734); *Frequency:* Yearly; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 9,200; *Total Annual Responses:* 9,200; *Total Annual Hours:* 2,900. (For policy questions regarding this collection contact Kari A Gaare at 410-786-8612.)

Dated: November 13, 2019.

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

4120-01-U-P

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