



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS-10638 and CMS-R-282]

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 also required to publish notice in the **Federal Register** concerning each proposed collection of information before the agency's request is submitted to OMB for approval.

DATES: Comments on the collection(s) of information must be received by the OMB desk officer by **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 60 days of publication of this notice to www.reginfo.gov/public/do/PRAMain . Find this particular information collection by selecting "Currently under 60-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, please access the CMS PRA web site by copying and pasting the following web address into your web browser: <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.

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.

Information Collection

1. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Add-On Payments for New Medical Services and Technologies Paid Under the Inpatient Prospective Payment System (IPPS); *Use:* Sections 1886(d)(5)(K) and (L) of the Act establish a process of identifying and ensuring adequate payment for new medical services and technologies (sometimes collectively referred to in this section as “new technologies”) under the Inpatient Prospective Payment System (IPPS). Section 1886(d)(5)(K)(vi) of the Act specifies that a medical service or technology will be considered new if it meets criteria established by the Secretary after notice and opportunity for public comment. Section 1886(d)(5)(K)(ii)(I) of the Act specifies that a new medical service or technology may be considered for NTAP if, “based on the estimated costs incurred with respect to discharges involving such service or technology, the DRG prospective payment rate otherwise applicable to such discharges under this subsection is inadequate.”

To qualify for NTAP under the traditional pathway, a specific technology must be “new” and demonstrate that they are not substantially similar to existing technologies under the requirements of § 412.87(b)(2) of our regulations. The statutory provision contemplated the

special payment treatment for new technologies until such time as data are available to reflect the cost of the technology in the DRG weights through recalibration (no less than 2 years and no more than 3 years). Alternative pathway technologies must also be “new” but are considered not substantially similar to existing technologies. Responses to the questions in the application help CMS determine if and how the applicant meets the established. *Form Number:* CMS-10638 (OMB control number: 0938-1347); *Frequency:* Yearly; *Affected Public:* Private Sector, Business or other for-profits and Not-for-profits institutions; *Number of Respondents:* 47; *Number of Responses:* 47; *Total Annual Hours:* 1,055. (For policy questions regarding this collection contact Drew Kasper at 410-786-8926.)

2. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Medicare Advantage Appeals and Grievance Data Form; *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. Medicare demonstrations also are required to conform to MA appeals regulations and thus are included in the count of organizations. Such demonstrations, as well as MA organizations, are collectively referred to as “MA plans” in this Supporting Statement. Data collection/disclosure categories are based on the MA plan’s grievance and appeals processes as prescribed under 42 CFR part 422, subpart M. *Form Number:* CMS-R-282 (OMB control number: 0938-0778); *Frequency:* Yearly; *Affected Public:* Private, Business or other for-profits and Not-for-profit institutions; *Number of Respondents:* 932; *Total Annual Responses:* 67,432;

Total Annual Hours: 6,252. (For policy questions regarding this collection contact Sabrina Edmonston at 410-786-3209 or sabrina.edmonston@cms.hhs.gov.)

William N. Parham, III

Director,

Division of Information Collections and Regulatory Impacts,

Office of Strategic Operations and Regulatory Affairs.

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