



## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **Centers for Medicare & Medicaid Services**

**[Document Identifiers: CMS-10638, CMS-R-5, CMS-287-19, and CMS-10088]**

#### **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](mailto: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](mailto: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:* Revision with change of a currently approved collection; *Title of Information Collection:* Application for New Medical Services and Technologies Seeking to Qualify for Add-On Payments Under the Hospital Inpatient Prospective Payment System; *Use:* Section 1886(d)(5)(K) authorizes the Secretary to establish a special payment methodology for new medical services and technologies used in inpatient procedures. To qualify for additional payments under this provision; a new technology must represent a substantial clinical improvement; data reflecting the cost of new technology must not yet be available in the data used to recalibrate the Medicare severity diagnosis-related groups (MS-DRGs); and the MS-DRG payment rate otherwise applicable to the new technology would be inadequate (see 42 CFR 412.87(b)). we are revising the estimated annual number of respondents from 32 to 62, based on the proposed alternative new technology add-on payment pathway for certain devices included in the FY 2020 IPPS proposed rule (CMS-1716-P). The existing regulations at 42 CFR 412.87 implement these provisions and specify three criteria for a new medical service or technology to receive the additional payment: (1) The medical service or

technology must be new; (2) the medical service or technology must be costly such that the DRG rate otherwise applicable to discharges involving the medical service or technology is determined to be inadequate; and (3) the service or technology must demonstrate a substantial clinical improvement over existing services or technologies.

In the FY 2020 IPPS proposed rule (84 FR 19371 - 19373), we proposed an alternative new technology add-on payment pathway for certain devices. Specifically, for applications received for new technology add-on payments for FY 2021 and subsequent fiscal years, we proposed that a medical device that has received Federal Drug Administration (FDA) marketing authorization (that is, has been approved or cleared by, or had a De Novo classification request granted by, the FDA) and that is part of the FDA's Breakthrough Devices Program would need to meet the cost criterion (that is, the medical device must be costly such that the DRG rate otherwise applicable to discharges involving the medical device is determined to be inadequate). To implement this proposal, we proposed to revise the existing regulations at 42 CFR 412.87. We use the application in order to determine if a technology meets the new technology criteria under the existing pathway, and would revise the application to reflect the information required to determine if a device meets the new technology criteria the proposed alternative pathway for certain devices. The revise application that would be used if the proposed alternative new technology add-on payment pathway for certain devices is finalized in the FY 2020 IPPS final rule, which is expected to be issued by August 1, 2019. *Form Number:* CMS-10638 (OMB control number: 0938-1347); *Frequency:* Yearly; *Affected Public:* Private Sector: Business or Other for-profits, Not for-profit Institutions; *Number of Respondents:* 62; *Total Annual*

*Responses: 62; Total Annual Hours: 1,655.* (For policy questions regarding this collection contact Michele Hudson at 410-786-5490.)

2. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Physician Certifications/Recertifications in Skilled Nursing Facilities Manual Instructions; *Use:* Section 1814(a) of the Social Security Act (the Act) requires specific certifications in order for Medicare payments to be made for certain services. Before the enactment of the Omnibus Budget Reconciliation Act of 1989 (OBRA1989, Public Law 101-239), section 1814(a)(2) of the Act required that, in the case of post-hospital extended care services, a physician certify that the services are or were required to be given because the individual needs or needed, on a daily basis, skilled nursing care (provided directly by or requiring the supervision of skilled nursing personnel) or other skilled rehabilitation services that, as a practical matter, can only be provided in a SNF on an inpatient basis. The physician certification requirements were included in the law to ensure that patients require a level of care that is covered by the Medicare program and because the physician is a key figure in determining the utilization of health services. In addition, it set forth qualification requirements that a nurse practitioner or clinical nurse specialist must meet in order to sign certification or recertification statements (these requirements were later revised in the Balanced Budget Act of 1997). Effective with items and services furnished on or after January 1, 2011, section 3108 of the Affordable Care Act added physician assistants to the existing authority for nurse practitioners and clinical nurse specialists. Regulations implementing this provision were promulgated in the calendar year (CY) 2011 Medicare Physician Fee Schedule (MPFS) final rule with comment

period (75 FR 73387, 73602, 73626-27, November 29, 2010). The requirements at 42 CFR 424.20(a) and (b) concern the initial certification of a beneficiary's need for a SNF level of care, which must be made upon admission or as soon thereafter as is reasonable and practicable. The requirements at 42 CFR 424.20(c) and (d) concern recertification of a beneficiary's need for continued SNF level of care, and also require an estimate of the time the individual will need to remain in the SNF, plans for home treatment, and, if appropriate, whether continued services are needed for a condition that occurred after admission to the SNF and while still receiving treatment for the condition for which he or she had received inpatient hospital services. These sections require recertification at specific intervals (the initial recertification must occur no later than the 14th day of SNF care, with subsequent recertification at least every 30 days thereafter) that posthospital SNF care is or was required because the individual needs or needed skilled care on a daily basis. The following CMS Internet-Only Manuals provide more detailed instructions regarding the required certification and recertification of covered post-hospital extended care services for a Medicare beneficiary: chapter 4, sections 40ff and 80 in the Medicare General Information, Eligibility, and Entitlement Manual (CMS Pub. 100-01), chapter 8, sections 40ff. in the Medicare Benefit Policy Manual (CMS Pub. 100-02), and chapter 6, section 6.3 in the Medicare Program Integrity Manual (CMS Pub. 100-08). *Form Number:* CMS-R-5 (OMB control number: 0938-0454); *Frequency:* Occasionally; *Affected Public:* Private Sector (Not-for-profit institutions); *Number of Respondents:* 2,746,550; *Total Annual Responses:* 2,746,550; *Total Annual Hours:* 615,149. (For policy questions regarding this collection contact Kia Sidbury at 410-786-7816.)

3. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Home Office Cost Statement; *Use:* Home offices of chain organizations vary greatly in size, number of locations, staff, mode of operations, and services furnished to the facilities in the chain. The home office of a chain is not in itself certified by Medicare. The relationship of the home office is that of a related organization to participating providers (See 42 CFR 413.17). When a provider claims costs on its cost report that are allocated from a home office, the Home Office Cost Statement constitutes the documentary support required of the provider to be reimbursed for home office costs in the provider's cost report. Each contractor servicing a provider in a chain must be furnished with a detailed Home Office Cost Statement as a basis for reimbursing the provider for cost allocations from a home office or chain organization. Home offices usually furnish central management and administrative services, e.g., centralized accounting, purchasing, personnel services, management direction and control, and other services. To the extent that the home office furnishes services related to patient care to a provider, the reasonable costs of such services are included in the provider's cost report and are reimbursable as part of the provider's costs. If the home office of the chain provides no services related to patient care, the costs of the home office may not be recognized in determining the allowable costs of the providers in the chain. Under the authority of sections 1815(a) and 1833(e) of the Social Security Act (42 USC 1395g), CMS requires that providers of services participating in the Medicare program submit information to determine costs for health care services rendered to Medicare beneficiaries. CMS requires that providers follow reasonable cost principles under 1861(v)(1)(A) of the Act when completing the

Medicare cost report. Under the regulations at 42 CFR 413.20 and 413.24, CMS defines adequate cost data and requires cost reports from providers on an annual basis. Providers receiving Medicare reimbursement must provide adequate cost data based on financial and statistical records, which can be verified by qualified auditors. The Form CMS-287-19 home office cost statement is needed to determine a provider's reasonable cost incurred in furnishing medical services to Medicare beneficiaries and reimbursement due to or from a provider. *Form Number:* CMS-287-19 (OMB control number: 0938-0202); *Frequency:* Annually; *Affected Public:* Private Sector (Business or other for-profit and Not-for-profit institutions); *Number of Respondents:* 1,507; *Total Annual Responses:* 1,507; *Total Annual Hours:* 702,262. (For policy questions regarding this collection contact Yaakov Feinstein at 410-786-3137.)

4. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Notification of FLS and CMS of Co-Located Medicare Providers; *Use:* Many long-term care hospitals (LTCHs) are co-located with other Medicare providers (acute care hospitals, inpatient rehabilitation facilities (IRFs), skilled nursing facilities (SNFs), inpatient psychiatric facilities (IPFs)), which could lead to potential gaming of the Medicare system based on inappropriate patient shifting. In regulations at 42 CFR 412.22(e)(3) and (h)(6) CMS requires LTCHs to notify Medicare Administrative Contractors (MACs) and CMS of co-located providers. The requirement regarding collection of information at §412.22 concerning a LTCH's (or a LTCH satellite's) notification to its MAC and CMS of its co-located status is needed in order for Medicare to appropriately pay co-located hospitals-within-hospitals (HwHs) and satellites. Under §§412.22(e)(3) and (h)(6), an LTCH or a satellite

of an LTCH that occupies space in a building used by another hospital, or in one or more entire buildings located on the same campus as buildings used by another hospital must notify its MAC and CMS in writing of its co-location within 60 days of its first cost reporting period that began on or after October 1, 2002. *Form Number:* CMS-10088 (OMB control number: 0938-0897); *Frequency:* Yearly; *Affected Public:* Private Sector (Business or other for-profit, not-for-profit institutions); *Number of Respondents:* 25; *Total Annual Responses:* 25; *Total Annual Hours:* 6. (For policy questions regarding this collection contact Emily Lipkin at 410-786-3633.)

Dated: December 12, 2019.

**William N. Parham, III,**

*Director, Paperwork Reduction Staff,*

*Office of Strategic Operations and Regulatory Affairs.*

4120-01-U-P

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