



Centers for Medicare & Medicaid Services

[Document Identifiers: CMS-381, CMS-10279, CMS-10774 and CMS-10636]

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 (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 [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

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, 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 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-381 Identification of Extension Units of Medicare Approved Outpatient Physical Therapy/Outpatient Speech Pathology (OPT/OSP) Providers and Supporting Regulations

CMS-10752 Submission of 1135 Waiver Request Automated Process

CMS-10774 The International Classification of Diseases, 10th Revision, Procedure Coding System (ICD-10-PCS)

CMS-10636 Triennial Network Adequacy Review for Medicare Advantage Organizations and 1876 Cost Plans

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 currently approved collection; *Title of Information Collection:* Identification of Extension Units of Medicare Approved Outpatient Physical Therapy/Outpatient Speech Pathology (OPT/OSP) Providers and Supporting Regulations; *Use:* Form CMS-381 was developed to ensure that each OPT/OSP extension location at which OPT/OSP providers furnish services, must be reported by the providers to the State Survey Agencies (SAs). Form CMS-381 is completed when: (1) new OPT/OSP providers enter the Medicare program; (2) when existing OPT/OPS providers delete or add a service, or close or add an extension location; or, (3) when existing OPT/OSP providers are recertified by the State Survey Agency every 6 years.

In 2022, CMS transitioned some of the certification processes to the Center for Program Integrity (CPI) and the Medicare Administrative Contractor (MAC). Prior to the transition, the CMS Survey Operations Group was involved in the processing of the extension location requests. As a result of the new processing instructions, CMS is now reconciling the Form CMS-381 with updates to the instructions. Additionally, CMS has revised the Form CMS-381 to incorporate the initial enrollment of OPT/OSPs which was previously completed on the Form CMS-1856 (0938-0065). CMS has combined the forms into one form in order to further align

with the transitioned processes and streamline the requests from the provider community. This change will decrease the burden on both the provider community as well as CMS. Furthermore, this change will also allow for OPTs who wish to initially enroll in the Medicare program to submit an extension location request with the initial enrollment. The State Survey Agency or Accrediting Organization (for those OPTs requesting deemed status) will survey the extension location during the initial survey to verify compliance with the Medicare conditions. *Form Number*: CMS-381 (OMB control number: 0938-0273); *Frequency*: Occasionally; *Affected Public*: Private Sector; Business or other for-profit and not-for-profit institutions; *Number of Respondents*: 506; *Total Annual Responses*: 506; *Total Annual Hours*: 253. (For policy questions regarding this collection contact Caecilia Andrews at 410-786-2190.)

2. *Type of Information Collection Request*: Revision of a currently approved collection; *Title of Information Collection*: Submission of 1135 Waiver Request Automated Process; *Use*: Waivers under section 1135 of the Social Security Act (the Act) and certain flexibilities allow the CMS to relax certain requirements, known as the Conditions of Participation (CoPs) or Conditions of Coverage to promote the health and safety of beneficiaries. Under section 1135 of the Act, the Secretary may temporarily waive or modify certain Medicare, Medicaid, and Children's Health Insurance Program (CHIP) requirements to ensure that sufficient health care services are available to meet the needs of individuals enrolled in Social Security Act programs in the emergency area and time periods. These waivers ensure that healthcare entities/caregivers who provide such services in good faith can be reimbursed and exempted from sanctions.

During emergencies, CMS must be able to apply program waivers and flexibilities under section 1135 of the Social Security Act, in a timely manner to respond quickly to unfolding events. In a disaster or emergency, waivers and flexibilities assist health care providers/suppliers in providing timely healthcare and services to people who have been affected and enables States, Federal districts, and U.S. Territories to ensure Medicare and/or Medicaid beneficiaries have

continued access to care. During disasters and emergencies, it is not uncommon to evacuate patients in health care facilities to other provider settings or across State lines, especially, during hurricane, wildfire, and tornado events. CMS must collect relevant information for which a provider is requesting a waiver or flexibility to make proper decisions about approving or denying such requests. Collection of this data aids in the prevention of gaps in access to care and services before, during, and after an emergency. CMS must also respond to inquiries related to a Public Health Emergency (PHE) from providers. CMS is not collecting information from these inquiries; we are merely responding to them.

The collection of the information surrounding 1135 Waiver requests/inquiries is based on a case-by-case basis and not regularly scheduled (e.g., quarterly, annually, by all providers/suppliers). The collection of information only occurs when the healthcare entity, impacted by an emergency, is requesting waivers/flexibilities under Section 1135 of the Act or inquiring about PHEs. The collection of information is also dependent on provider types; therefore, it is not a collection for all Medicare-participating facilities. In 2021, we implemented a streamlined, automated process to standardize the 1135 waiver requests and inquiries submitted based on lessons learned during the COVID-19 PHE.

Furthermore, the normal operations of a healthcare provider are disrupted by emergencies or disasters occasionally. When this occurs, State Survey Agencies (SA) deliver a provider/beneficiary tracking report regarding the current status of all affected healthcare providers and their beneficiaries. We are revising this information collection streamlined automated process to update for clarity during emergencies. To quickly identify patient risks/needs, CMS added fields to assess sufficient staffing, equipment and supplies as well as added an assessment of a cyber security attack on the care and services provided to patients (if applicable). Moreover, to decrease the time/effort of stakeholders (State Survey Agencies (SAs)/Providers) submitting this data during emergencies, CMS also added a feature to autofill multiple fields when the stakeholder documents a valid CMS Certification Number (CCN).

This streamlined automated process will consist of a public facing web form as well as a process for SAs/Providers to submit data using extracts (CSV or Excel) on emergent events impacting Health Care Facilities via automated mail handler system. Both processes (public facing web form and extracts via an automated mail handler system) are known as the Health Care Facility (HCF) Operational Status. Finally, Acute Hospital Care at Home waiver is granted at the individual hospital/CMS Certification Number (CCN) level and waives §482.23(b) and (b)(1) of the Hospital Conditions of Participation (CoPs) which require nursing services to be provided on premises 24 hours a day, 7 days a week and the immediate availability of a registered nurse for care of any patient (This waiver allows hospitals to utilize models of *at-home* hospital care). This Acute Hospital Care at Home web form was revised to add questions for the respondents to meet requirements for all hospitals for (1) the Patient Rights CoP at 42 CFR 482.13, (2) the Consolidated Appropriations Act of 2023 and (3) for emergency response. *Form Number:* CMS-10752 (OMB control number: 0938-1384); *Frequency:* Occasionally; *Affected Public:* Private Sector: Business or other for-profits and Not-for-profit institutions and State, Local or Tribal Governments; *Number of Respondents:* 1,020; *Total Annual Responses:* 11,916; *Total Annual Hours:* 11,916. (For policy questions regarding this collection, contact Adriane Saunders at 404-562-7484.)

3. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* The International Classification of Diseases, 10th Revision, Procedure Coding System (ICD-10-PCS); *Use:* The HIPAA Act of 1996 required CMS to adopt standards for coding systems that are used for reporting health care transactions. The Transactions and Code Sets final rule (65 FR 50312) published in the **Federal Register** on August 17, 2000 adopted the International Classification of Diseases, 9th Revision, Clinical Modification (ICD-9-CM) Volumes 1 and 2 for diagnosis codes and ICD-9-CM Volume 3 for inpatient hospital services and procedures as standard code sets for use by covered entities (health plans, health care clearinghouses, and those health care providers who transmit any

health information in electronic form in connection with a transaction for which the Secretary has adopted a standard). ICD-9-CM Volumes 1 and 2, and ICD-9-CM Volume 3 were already widely used in administrative transactions when we promulgated the August 17, 2000 final rule, and we decided that adopting these existing code sets would be less disruptive for covered entities than modified or new code sets.

When a request is submitted in MEARIST™, the Diagnosis Related Groups (DRGs) and Coding Team in the Division of Coding and DRGs (DCDRG) have instant access to the request and accompanying materials to facilitate a more-timely review of the proposed updates or changes. Upon receipt of a procedure code request, CMS immediately acknowledges receipt of the request and communicates to the requestor that additional follow up will occur once an analyst has been assigned. In addition, CMS provides information via email communication in a letter to each requestor outlining the meeting process. CMS holds standard pre-meeting conference calls with requestors to discuss their procedure code topic request in more detail in advance of the ICD-10 C&M Committee Meetings. Also, prior to the committee meeting, we make the procedure code topic meeting materials publicly available, commonly referred to as the “Agenda packet” on our website at:

<https://www.cms.gov/medicare/coding-billing/icd-10-codes/icd-10-coordination-maintenance-committee-materials>. Lastly, once the meeting has concluded, CMS sends a follow-up letter to the requestor informing them of next steps in the process so they can anticipate what to expect. *Form Number:* CMS-10774 (OMB control number: 0938-1409); *Frequency:* Yearly; *Affected Public:* Private Sector; Business or other for-profit and not-for-profit institutions; *Number of Respondents:* 80; *Total Annual Responses:* 80; *Total Annual Hours:* 800. (For policy questions regarding this collection contact Andrea Hazeley at 410-786-3543.)

4. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Triennial Network Adequacy Review for Medicare Advantage Organizations and 1876 Cost Plans; *Use:* This collection of information request is

authorized under section 1852(d)(1) of the Social Security Act which permits an MA organization to select the providers from which an enrollee may receive covered benefits, provided that the MA organization makes such benefits available and accessible in the service area with promptness and in a manner which assures continuity in the provision of benefits as defined in §§422.112(a)(1)(i) and 422.114(a)(3)(ii) (under Part 422, Subpart C – benefits and beneficiary protections) and §§417.414(b) and 417.416(a) and (e) (under Part 417, Subpart J – Qualifying Conditions for Medicare Contracts).

The information will be collected by CMS through HPMS. CMS measures access to covered services through the establishment of quantitative standards for a predefined list of provider and facility specialty types. These quantitative standards are collectively referred to as the network adequacy criteria. Network adequacy is assessed at the county level and CMS requires that organizations contract with a sufficient number of providers and facilities to ensure that at least 90 percent of enrollees within a county can access care within specific travel time and distance maximums for Large Metro and Metro county types and that at least 85 percent of enrollees within a county can access care within specific travel time and distance maximums for Micro, Rural and CEAC (Counties with Extreme Access Considerations county types. *Form Number: CMS-10636 (OMB control number: 0938-1346); Frequency: Yearly; Affected Public: Private Sector; Business or other for-profit; Number of Respondents: 502; Total Annual Responses: 2,753; Total Annual Hours: 27,470.* (For policy questions regarding this collection contact Amber Casserly at 410-786-5530.)

William N. Parham, III

Director,

Division of Information Collections and Regulatory Impacts,

Office of Strategic Operations and Regulatory Affairs.

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