

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Centers for Medicare & Medicaid Services**

[Document Identifiers: CMS–216–94 and CMS–1984–14]

**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 August 26, 2024.

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 website 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–216–94 Organ Procurement Organization (OPO)/Histocompatibility Laboratory (HCL) Cost Report Form
CMS–1984–14 Hospice Facility Cost Report

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:* Extension of a currently approved collection; *Title of Information Collection:* Organ Procurement Organization Histocompatibility Laboratory Cost Report; *Use:* The Form CMS–216–94 cost report is needed to determine Organ Procurement Organization (OPO)/Histocompatibility Lab (HL) reasonable costs incurred in procuring and transporting organs for transplant into Medicare beneficiaries and reimbursement due to or from the provider. The reasonable costs of procuring and transporting organs cannot be determined for the fiscal year

until the OPO/HL files its cost report and costs are verified by the Medicare contractor. During the fiscal year, an interim rate is established based on cost report data from the previous year. The OPO/HL bills the transplant hospital for services rendered. The transplant hospital pays interim payments, approximating reasonable cost, to the OPO/HL. The Form CMS–216–94 cost report is filed by each OPO/HL at the end of its fiscal year and there is a cost report settlement to take into account increases or decreases in costs. The cost report reconciliation and settlement take into consideration the difference between the total reasonable costs minus the total interim payments received or receivable from the transplant centers. *Form Number:* CMS–216–94 (OMB control number: 0938–0102); *Frequency:* Annually; *Affected Public:* Private Sector—Business or other for-profits; *Number of Respondents:* 95; *Total Annual Responses:* 95; *Total Annual Hours:* 4,275. (For policy questions regarding this collection contact Luann Piccione at 410–786–5423.)

2. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Hospice Facility Cost Report Form; *Use:* Under the authority of sections 1815(a) and 1833(e) of the Social Security Act (the Act), 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 (MCR). The regulations at 42 CFR 413.20 and 413.24 require that providers submit acceptable cost reports on an annual basis and maintain sufficient financial records and statistical data, capable of verification by qualified auditors. In addition, regulations require that providers furnish such Information to the contractor as may be necessary to assure proper payment by the program, receive program payments, and satisfy program overpayment determinations.

CMS regulations at 42 CFR 413.24(f)(4) require that each hospice submit an annual cost report to their contractor in a standard American Standard Code for Information Interchange (ASCII) electronic cost report (ECR) format. A hospice submits the ECR file to contractors using a compact disk (CD), flash drive, or the CMS approved Medicare Cost Report E-filing (MCREF) portal, [URL: <https://mcref.cms.gov>]. The instructions for

submission are included in the hospice cost report instructions on page 43–3.

CMS requires the Form CMS–1984–14 to determine a hospice's reasonable costs incurred in furnishing medical services to Medicare beneficiaries. CMS uses the Form CMS–1984–14 for rate setting; payment refinement activities, including developing a market basket; Medicare Trust Fund projections; and program operations support. Additionally, the Medicare Payment Advisory Commission (MedPAC) uses the hospice cost report data to calculate Medicare margins (a measure of the relationship between Medicare's payments and providers' Medicare costs) and analyze data to formulate Medicare Program recommendations to Congress. *Form Number:* CMS–1984–14 (OMB control number: 0938–0758); *Frequency:* Yearly; *Affected Public:* Private Sector, Business or other for-profits, Not for profits institutions; *Number of Respondents:* 6,430; *Total Annual Responses:* 6,430; *Total Annual Hours:* 1,208,840. (For policy questions regarding this collection contact Duncan Gail at 410–786–7278.)

William N. Parham, III,

Director, Division of Information Collections and Regulatory Impacts, Office of Strategic Operations and Regulatory Affairs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–3461–PN]

Medicare and Medicaid Programs: Application by the Accreditation Association for Ambulatory Health Care for Continued CMS-Approval of Ambulatory Surgical Center Accreditation Program

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Proposed notice.

SUMMARY: This proposed notice announces the receipt of an application from the Accreditation Association for Ambulatory Health Care for continued recognition as a national accrediting organization for Ambulatory Surgical Centers that wish to participate in the Medicare or Medicaid programs.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on July 29, 2024.

ADDRESSES: In commenting, refer to file code CMS–3461–PN. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

Comments, including mass comment submissions, must be submitted in one of the following three ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to <http://www.regulations.gov>. Follow the “Submit a comment” instructions.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–3461–PN, P.O. Box 8010, Baltimore, MD 21244–8010.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–3461–PN, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: Joy Webb, (410) 786–1667, Joann Fitzell, (410) 786–4280.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following website as soon as possible after they have been received: <http://www.regulations.gov>. Follow the search instructions on that website to view public comments. CMS will not post on *Regulations.gov* public comments that make threats to individuals or institutions or suggest that the commenter will take actions to harm an individual. CMS continues to encourage individuals not to submit duplicative comments. We will post acceptable comments from multiple unique commenters even if the content is identical or nearly identical to other comments.

I. Background

Ambulatory Surgical Centers (ASCs) are distinct entities that operate exclusively for the purpose of

furnishing outpatient surgical services to patients. Under the Medicare program, eligible beneficiaries may receive covered services from an ASC provided certain requirements are met. Section 1832(a)(2)(F)(i) of the Social Security Act (the Act) establishes distinct criteria for a facility seeking designation as an ASC. Regulations concerning provider agreements are at 42 CFR part 489 and those pertaining to activities relating to the survey and certification of facilities are at 42 CFR part 488. The regulations at 42 CFR part 416 specify the conditions that an ASC must meet in order to participate in the Medicare program, the scope of covered services, and the conditions for Medicare payment for ASCs.

Generally, to enter into an agreement, an ASC must first be certified by a state survey agency (SA) as complying with the conditions or requirements set forth in part 416 of our Medicare regulations. Thereafter, the ASC is subject to regular surveys by an SA to determine whether it continues to meet these requirements.

Section 1865(a)(1) of the Act provides that, if a provider entity demonstrates through accreditation by a Centers for Medicare & Medicaid Services (CMS) approved national accrediting organization (AO) that all applicable Medicare conditions are met or exceeded, we may deem that provider entity as having met the requirements. Accreditation by an AO is voluntary and is not required for Medicare participation.

If an AO is recognized by the Secretary of the Department of Health and Human Services as having standards for accreditation that meet or exceed Medicare requirements, any provider entity accredited by the national accrediting body's approved program may be deemed to meet the Medicare conditions. The AO applying for approval of its accreditation program under part 488, subpart A, must provide CMS with reasonable assurance that the AO requires the accredited provider entities to meet requirements that are at least as stringent as the Medicare conditions. Our regulations concerning the approval of AOs are set forth at §§ 488.4 and 488.5.

The Accreditation Association for Ambulatory Health Care's (AAAHC's) current term of approval for its ASC program expires December 20, 2024.

II. Approval of Deeming Organization

Section 1865(a)(2) of the Act and our regulations at § 488.5 require that our findings concerning review and approval of an AO's requirements consider, among other factors, the applying AO's requirements for