DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–1500/1490S and CMS–R–234]

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 June 25, 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–1500/1490 Health Insurance Common Claims Form and Supporting Regulations at 42 CFR part 424, subpart C

CMS–R–234 Subpart D—Private Contracts and Supporting Regulations in 42 CFR 405.410, 405.430, 405.435, 405.440, 405.445, 405.455, 410.61, 415.110, and 424.24

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:* Extension without change of a currently approved collection; *Title of Information Collection:* Health Insurance Common Claims Form and Supporting Regulations at 42 CFR part 424, subpart C; *Use:* The CMS–1500 and the CMS–1490S forms are used to deliver information to CMS for CMS to reimburse for provided services. Medicare Administrative Contractors use the data collected on the CMS–1500 and the CMS–1490S to determine the proper amount of reimbursement for Part B medical and other health services (as listed in section 1861(s) of the Social Security Act) provided by physicians and suppliers to beneficiaries. The CMS–1500 is submitted by physicians/suppliers for all Part B Medicare. Serving as a common claim form, the CMS–1500 can be used by other third-party payers (commercial and nonprofit health insurers) and other Federal programs (*e.g.,* TRICARE, RRB, and Medicaid). *Form Number:* CMS–1500/1490S (OMB control number: 0938–1197); *Frequency:* Occasionally; *Affected Public:* Private Sector: Business or other for-profit and not-for-profit institutions; *Number of Respondents:* 2,507,992; *Total Annual Responses:* 994,038,623; *Total Annual Hours:* 17,328,912. (For policy questions regarding this collection contact Sadaf Ali-Simpson at 667–414–0004.)

2. *Type of Information Collection Request:* Reinstatement without change of a previously approved collection; *Title of Information Collection:* Subpart D-Private Contracts and Supporting Regulations in 42 CFR 405.410, 405.430, 405.435, 405.440, 405.445, 405.455, 410.61, 415.110, and 424.24; *Use:* Section 4507 of the Balanced Budget Act of 1997 (BBA 1997) amended section 1802 of the Social Security Act (the Act) to permit certain physicians and practitioners to opt-out of Medicare and to provide—through private contracts—services that Medicare would otherwise cover. Under such contracts, the mandatory claims submission and limiting charge rules of section 1848(g) of the Act would not apply. CMS–R–234 allows certain physicians and practitioners to opt out of Medicare and furnish covered services to Medicare beneficiaries through private contracts. Physicians and practitioners use this information collection to comply with the applicable regulations. Physicians and practitioners entering private contracts with beneficiaries must file an affidavit with Medicare in which they agree to opt-out of Medicare for 2 years and to meet certain other criteria. In general, the applicable regulations require that during that 2-year period, physicians and practitioners who have filed affidavits opting out of Medicare must sign private contracts with all Medicare beneficiaries to whom they furnish services that Medicare would otherwise cover (except those who need emergency or urgently needed care). In addition, Medicare Administrative Contractors (MACs) use this information to determine if benefits should be paid or continued. *Form Number:* CMS–R–234 (OMB control number: 0938–0730);

Frequency: Occasionally; *Affected Public:* Business or other for-profit and not-for-profit institutions; *Number of Respondents;* 78,258; *Total Annual Responses;* 78,258; *Total Annual Hours:* 22,780. (For policy questions regarding this collection contact Frank Whelan at 410–786–1302.)

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–3464–PN]

Medicare Program; Application by the National Association of Boards of Pharmacy (NABP) for Continued CMS Approval of its Home Infusion Therapy (HIT) Accreditation Program

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

ACTION: Notice with request for comment.

SUMMARY: This notice acknowledges the receipt of an application from the National Association of Boards of Pharmacy (NABP) for continued approval by the Centers for Medicare & Medicaid Services (CMS) of NABP's national accrediting organization program for suppliers providing home infusion therapy (HIT) services and that wish to participate in the Medicare or Medicaid programs. The statute requires that within 60 days of receipt of an organization's complete application, CMS will publish a notice that identifies the national accrediting body making the request, describes the nature of the request, and provides at least a 30-day public comment period.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, by May 28, 2024.

ADDRESSES: In commenting, refer to file code CMS–3464–PN.

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–3464–PN, P.O. Box 8016, 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–3464–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: Shannon Freeland, (410) 786–4348.

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. We will not post on *Regulations.gov* public comments that make threats to individuals or institutions or suggest that the individual will take actions to harm the individual. We continue 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

Home infusion therapy (HIT) is a treatment option for Medicare beneficiaries with a wide range of acute and chronic conditions. Section 5012 of the 21st Century Cures Act (Pub. L. 114–255, enacted December 13, 2016) added section 1861(iii) to the Social Security Act (the Act), establishing a new Medicare benefit for HIT services. Section 1861(iii)(1) of the Act defines ''home infusion therapy'' as professional services, including nursing services; training and education not otherwise covered under the Durable Medical Equipment (DME) benefit; remote monitoring; and other monitoring services. HIT must be furnished by a qualified HIT supplier and furnished in the individual's home. The individual must:

- Be under the care of an applicable provider (that is, physician, nurse practitioner, or physician assistant); and
- Have a plan of care established and periodically reviewed by a physician in coordination with the furnishing of home infusion drugs under Part B, that prescribes the type, amount, and duration of infusion therapy services that are to be furnished.

Section 1861(iii)(3)(D)(i)(III) of the Act requires that a qualified HIT supplier be accredited by an accrediting organization (AO) designated by the Secretary in accordance with section 1834(u)(5) of the Act. Section 1834(u)(5)(A) of the Act identifies factors for designating AOs and in reviewing and modifying the list of designated AOs. These statutory factors are as follows:

- The ability of the organization to conduct timely reviews of accreditation applications.
- The ability of the organization to take into account the capacities of suppliers located in a rural area (as defined in section 1886(d)(2)(D) of the Act).
- Whether the organization has established reasonable fees to be charged to suppliers applying for accreditation.
- Such other factors as the Secretary determines appropriate.

Section 1834(u)(5)(B) of the Act requires the Secretary to designate AOs to accredit HIT suppliers furnishing HIT no later than January 1, 2021. Section 1861(iii)(3)(D)(i)(III) of the Act requires a ''qualified home infusion therapy supplier'' to be accredited by a CMS-approved AO, pursuant to section 1834(u)(5) of the Act.

On March 1, 2019, we published a solicitation notice entitled, ''Medicare Program; Solicitation of Independent Accrediting Organizations to Participate in the Home Infusion Therapy Supplier Accreditation Program'' (84 FR 7057). This notice informed national AOs that accredit HIT suppliers of an opportunity to submit applications to participate in the HIT supplier accreditation program. We stated that complete applications would be considered for the January 1, 2021 designation deadline if received by February 1, 2020. Regulations for the approval and oversight of AOs for HIT organizations are located at 42 CFR part 488, subpart L. The requirements for HIT suppliers are located at 42 CFR part 486, subpart I.

II. Approval of Deeming Organization

Section 1834(u)(5) of the Act and regulations at 42 CFR 488.1010 require that our findings concerning review and approval of a national accrediting