Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35).

V. Response to Comments

Because of the large number of public comments, we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this notice.

Upon completion of our evaluation, including evaluation of comments received as a result of this notice, we will publish a final notice in the **Federal Register** summarizing our response to comments and announcing the result of our evaluation.

The Administrator of the Centers for Medicare & Medicaid Services (CMS), Seema Verma, having reviewed and approved this document, authorizes Lynette Wilson, who is the Federal Register Liaison, to electronically sign this document for purposes of publication in the **Federal Register**.

Dated: September 22, 2020.

Lynette Wilson,

Federal Register Liaison, Centers for Medicare & Medicaid Services.

[FR Doc. 2020–21262 Filed 9–25–20; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–10393, CMS–10525 and CMS–10593]

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 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 October 28, 2020.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-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, you may make your request using one of following:

1. Access CMS' website address at website address at *https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html.*

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:* Extension of a previously approved collection; *Title of Information Collection:* Beneficiary and Family Centered Data Collection; *Use:* To ensure the QIOs are effectively meeting their goals, CMS collects information about beneficiary experience receiving support from the QIOs. The information collection uses both qualitative and quantitative strategies to ensure CMS and the QIOs understand beneficiary experiences through all interactions with the QIO including initial contact, interim interactions, and case closure. Information collection instruments are tailored to reflect the steps in each type of process, as well as the average time it takes to complete each process. The information collection will:

- Allow beneficiaries to directly provide feedback about the services they receive under the QIO program;
- Provide quality improvement data for QIOs to improve the quality of service delivered to Medicare beneficiaries; and
- Provide evaluation metrics for CMS to use in assessing performance of QIO contractors.

To achieve the above goals, information collection will include: Experience survey, direct follow-up and general feedback web survey. *Form Number:* CMS–10393 (OMB control number: 0938–1177); *Frequency:* Once; *Affected Public:* Individuals or households; *Number of Respondents:* 9,100; *Number of Responses:* 9,100; *Total Annual Hours:* 2,191. (For policy questions regarding this collection, contact David Russo at 617–565–1310.)

2. *Type of Information Collection Request:* Re-instatement with change of a previously approved collection; *Title:* PACE Quality Data Monitoring and Reporting; *Use:* The Programs of All-Inclusive Care for the Elderly (PACE) program is a unique model of managed care service delivery for the frail elderly, most of whom are dually-eligible for Medicare and Medicaid benefits. To be eligible to enroll in PACE, an individual must: Be 55 or older, live in the service area of a PACE organization (PO), need a nursing home-level of care (as certified by the state in which he or she lives), and be able to live safely in the community with assistance from PACE.

PACE organizations are responsible for providing all required Medicare and Medicaid covered services, and any other service that the interdisciplinary team (IDT) determines necessary to improve and maintain a participant's overall health condition (42 CFR 460.92). POs must also comply with the quality monitoring and reporting requirements outlined in §§ 460.140, 460.200(b)(1), 460.200(c) and 460.202. POs are also required to report certain unusual incidents to other Federal and

State agencies consistent with applicable statutory or regulatory requirements (see 42 CFR 460.136(a)(5)). *Form Number:* CMS–10525 (OMB control number: 0938–1264); *Frequency:* Annual; *Affected Public:* Private Sector: Business or other for-profits; *Number of Respondents:* 134; *Total Annual Responses:* 1,143; *Total Annual Hours:* 173,664. (For policy questions regarding this collection contact Donna Williamson at 410–786–4647.)

3. *Type of Information Collection Request:* Reinstatement; *Title of Information Collection:* Establishment of an Exchange by a State and Qualified Health Plans; *Use:* The Patient Protection and Affordable Care Act, Public Law 111–148, enacted on March 23, 2010, and the Health Care and Education Reconciliation Act, Public Law 111–152, enacted on March 30, 2010 (collectively, ''Affordable Care Act''), expand access to health insurance for individuals and employees of small businesses through the establishment of new Affordable Insurance Exchanges (Exchanges), including the Small Business Health Options Program (SHOP).

As directed by the rule *Establishment of Exchanges and Qualified Health Plans; Exchange Standards for Employers* (77 FR 18310) (Exchange rule), each Exchange will assume responsibilities related to the certification and offering of Qualified Health Plans (QHPs). To offer insurance through an Exchange, a health insurance issuer must have its health plans certified as QHPs by the Exchange. A QHP must meet certain minimum certification standards, such as network adequacy, inclusion of Essential Community Providers (ECPs), and non-discrimination. The Exchange is responsible for ensuring that QHPs meet these minimum certification standards as described in the Exchange rule under 45 CFR 155 and 156, based on the Affordable Care Act, as well as other standards determined by the Exchange. The reporting requirements and data collection in the Exchange rule address Federal requirements that various entities must meet with respect to the establishment and operation of an Exchange; minimum requirements that health insurance issuers must meet with respect to participation in a State based or Federally-facilitated Exchange; and requirements that employers must meet with respect to participation in the SHOP and compliance with other provisions of the Affordable Care Act. *Form Number:* CMS–10593 (OMB Control Number: 0938–1312); *Frequency:* Monthly, Annual; *Affected Public:* Private Sector; *Number of Respondents:* 20; *Number of Responses:* 361; *Total Annual Hours:* 51,805. (For policy questions regarding this collection contact Courtney Williams at 301–492–5157.)

Dated: September 23, 2020.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2020–21384 Filed 9–25–20; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–3386–FN]

Medicare Program; Approval of Application by The Compliance Team for Initial CMS-Approval of Its Home Infusion Therapy Accreditation Program

AGENCY: Centers for Medicare and Medicaid Services, HHS.

ACTION: Final notice.

SUMMARY: This final notice announces our decision to approve The Compliance Team for initial recognition as a national accrediting organization for home infusion therapy suppliers that wish to participate in the Medicare program. A home infusion therapy supplier that participates must meet the Medicare conditions for coverage.

DATES: The approval announced in this final notice takes effect October 1, 2020 through October 1, 2024.

FOR FURTHER INFORMATION CONTACT: Christina Mister-Ward, (410) 786–2441. Shannon Freeland, (410) 786–4348. Lillian Williams, (410) 786–8636.

SUPPLEMENTARY INFORMATION:

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 on December 13, 2016) added sections 1861(iii) and 1834(u) to the Social Security Act (the Act), establishing a new Medicare benefit for HIT services. Section 1861(iii)(1) of the Act defines HIT 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. Home infusion therapy 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 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 not later than January 1, 2021. Section 1861(iii)(3)(D) of the Act defines ''qualified home infusion therapy suppliers'' as being accredited by a CMS-approved AO.

In the March 1, 2019 **Federal Register**, 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. Complete applications will 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 Accreditation Organizations

Section 1834(u)(5) of the Act and the regulations at § 488.1010 require that our findings concerning review and