

(5) Recommendation with rationale for one of the two bases (crosswalking or gapfilling) for determining payment for reconsidered and new tests.

In addition, presenters should provide the data on which their recommendations are based. Presentations regarding reconsidered and new test codes that do not address the above five items for presenters may be considered incomplete and may not be considered by CMS when making a determination. However, we may request missing information following the meeting to prevent a recommendation from being considered incomplete.

Taking into account the comments and recommendations (and accompanying data) received at the CLFS Annual Public Meeting, we intend to post our proposed determinations with respect to the appropriate basis for establishing a payment amount for each new test code and our preliminary determinations with respect to the reconsidered codes along with an explanation of the reasons for each determination, the data on which the determinations are based, and a request for public written comments on these determinations on our website by early September 2020. This website can be accessed at <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/index.html?redirect=/ClinicalLabFeeSched/>. Interested parties may submit written comments on the preliminary determinations for new and reconsidered codes by early October 2020, to the address specified in the **ADDRESSES** section of this notice or electronically to our CLFS dedicated email box, [CLFS\\_Annual\\_Public\\_Meeting@cms.hhs.gov](mailto:CLFS_Annual_Public_Meeting@cms.hhs.gov) (the specific date for the publication of the determinations on the CMS website, as well as the deadline for submitting comments regarding the determinations, will be published on the CMS website). Final determinations for new test codes to be included for payment on the CLFS for CY 2021 and reconsidered codes will be posted on our website in November 2020, along with the rationale for each determination, the data on which the determinations are based, and responses to comments and suggestions received from the public. The final determinations with respect to reconsidered codes are not subject to further reconsideration. With respect to the final determinations for new test codes, the public may request reconsideration of the basis and amount of payment as set forth in § 414.509.

### III. Registration Instructions

The Division of Ambulatory Services in the CMS Center for Medicare is coordinating the CLFS Annual Public Meeting registration. Beginning May 1, 2020 and ending June 4, 2020, registration may be completed only by presenters. Individuals who intend to view and/or listen to the meeting do not need to register. Presenter registration may be completed by sending an email to our CLFS dedicated email box, [CLFS\\_Annual\\_Public\\_Meeting@cms.hhs.gov](mailto:CLFS_Annual_Public_Meeting@cms.hhs.gov). The subject of the email should state "Presenter Registration for CY 2021 CLFS Annual Laboratory Meeting." All of the following information must be submitted when registering:

- Speaker name.
- Organization or company name.
- Telephone numbers.
- Email address that will be used by the presenter in order to connect to the virtual meeting.
  - New or Reconsidered Code (s) for which presentation is being submitted.
  - Presentation.

Registration details may not be revised once they are submitted. If registration details require changes, a new registration entry must be submitted by the date specified in the **DATES** section of this notice. In addition, registration information must reflect individual-level content and not reflect an organization entry. Also, each individual may only register one person at a time. That is, one individual may not register multiple individuals at the same time.

When registering, individuals must also specify the new or reconsidered test codes on which they will be presenting comments. A confirmation email will be sent upon receipt of the registration. The email will provide information to the presenter in preparation for the meeting. Registration is only required for individuals giving a presentation during the meeting. Presenters must register by the deadline specified in the **DATES** section of this notice.

If you are not presenting during the CLFS Annual Public Meeting, you may view the meeting via webinar or listen-only by teleconference. If you would like to listen to or view the meeting, teleconference dial-in and webinar information will appear on the final CLFS Annual Public Meeting agenda, which will be posted on the CMS website when available at <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/index.html?redirect=/ClinicalLabFeeSched/>.

### VI. Special Accommodations

Individuals viewing or listening to the meeting who are hearing or visually impaired and have special requirements, or a condition that requires special assistance, should send an email to the resource box ([CDLT\\_Annual\\_Public\\_Meeting@cms.hhs.gov](mailto:CDLT_Annual_Public_Meeting@cms.hhs.gov)). The deadline for submitting this request is listed in the **DATES** section of this notice.

### VII. Collection of Information Requirements

This document does not impose information collection requirements, that is, reporting, recordkeeping or third-party disclosure requirements. Consequently, there is no need for review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

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

Dated: April 28, 2020.

**Evell J. Barco Holland**,  
Federal Register Liaison, Department of Health and Human Services.

[FR Doc. 2020-09390 Filed 5-1-20; 8:45 am]

**BILLING CODE 4120-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

[CMS-3386-PN2]

### Medicare Program; Application From The Compliance Team for Initial CMS Approval of its Home Infusion Therapy Accreditation Program

**AGENCY:** Centers for Medicare and Medicaid Services, HHS.

**ACTION:** Notice with request for comment.

**SUMMARY:** This proposed notice acknowledges the receipt of an application from The Compliance Team (TCT) for initial recognition as a national accrediting organization for suppliers of home infusion therapy services that wish to participate in the Medicare program. The statute requires that within 60 days of receipt of an organization's complete application, we 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, no later than 5 p.m. on June 3, 2020.

**ADDRESSES:** In commenting, please refer to file code CMS-3386-PN2.

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-3386-PN2, P.O. Box 8016, Baltimore, MD 21244-8016.

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-3386-PN2, 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:**

Christina Mister-Ward, (410) 786-2441.

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.

## 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. 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)(i)(III) of the Act requires a "qualified home infusion therapy supplier" to be accredited by a CMS-approved AO, under section 1834(u)(5) of the Act.

On March 1, 2019, we published a solicitation notice entitled, "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 Accreditation Organizations

Section 1834(u)(5) of the Act and the regulations at § 488.1010 require that our findings concerning review and approval of a national AO's requirements consider, among other factors, the applying AO's requirements for accreditation; survey procedures; resources for conducting required surveys; capacity to furnish information for use in enforcement activities; monitoring procedures for provider entities found not in compliance with the conditions or requirements; and ability to provide us with the necessary data.

Section 488.1020(a) requires that we publish, after receipt of an organization's complete application, a notice identifying the national accrediting body making the request, describing the nature of the request, and providing at least a 30-day public comment period. In accordance with § 488.1010(d), we have 210 days from the receipt of a complete application to publish notice of approval or denial of the application.

The purpose of this proposed notice is to inform the public of The Compliance Team's (TCT's) initial request for our approval of its HIT accreditation program. This notice also solicits public comment on whether TCT's requirements meet or exceed the Medicare conditions of participation for HIT services.

## III. Evaluation of Deeming Authority Request

TCT submitted all the necessary materials to enable us to make a determination concerning its request for initial approval of its HIT accreditation program. This application was determined to be complete on March 4, 2020. Under section 1834(u)(5) of the Act and § 488.1010 (Application and re-application procedures for national HIT AOs), our review and evaluation of TCT will be conducted in accordance with, but not necessarily limited to, the following factors:

- The equivalency of TCT's standards for HIT as compared with CMS' HIT conditions for certification.
- TCT's survey process to determine the following:
  - ++ The composition of the survey team, surveyor qualifications, and the

ability of the organization to provide continuing surveyor training.

++ The comparability of TCT's to our standards and processes, including survey frequency, and the ability to investigate and respond appropriately to complaints against accredited facilities.

++ TCT's processes and procedures for monitoring a HIT supplier found out of compliance with TCT's program requirements.

++ TCT's capacity to report deficiencies to the surveyed supplier and respond to the suppliers' plan of correction in a timely manner.

++ TCT's capacity to provide us with electronic data and reports necessary for effective assessment and interpretation of the organization's survey process.

++ The adequacy of TCT's staff and other resources, and its financial viability.

++ TCT's capacity to adequately fund required surveys.

++ TCT's policies with respect to whether surveys are announced or unannounced, to assure that surveys are unannounced.

++ TCT's agreement to provide us with a copy of the most current accreditation survey together with any other information related to the survey as we may require (including corrective action plans).

- TCT's agreement or policies for voluntary and involuntary termination of suppliers.

- TCT agreement or policies for voluntary and involuntary termination of the HIT AO program.

- TCT's policies and procedures to avoid conflicts of interest, including the appearance of conflicts of interest, involving individuals who conduct surveys or participate in accreditation decisions

#### IV. Collection of Information Requirements

This document does not impose information collection and requirements, that is, reporting, recordkeeping or third party disclosure requirements. Consequently, there is no need for review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*)

#### V. Response to Public 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 preamble, and, when we proceed with a subsequent document, we will

respond to the comments in the preamble to that document.

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** 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 Evell J. Barco Holland, who is the Federal Register Liaison, to electronically sign this document for purposes of publication in the **Federal Register**.

Dated: April 21, 2020.

**Evell J. Barco Holland,**

*Federal Register Liaison, Department of Health and Human Services.*

[FR Doc. 2020-09393 Filed 5-1-20; 8:45 am]

**BILLING CODE 4120-01-P**

### DEPARTMENT OF HEALTH AND HUMAN SERVICES

#### Centers for Medicare & Medicaid Services

[Document Identifier: CMS-10287 and CMS-10540]

#### Agency Information Collection Activities: Proposed Collection; 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 (the 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 July 6, 2020.

**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, 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. Email your request, including your address, phone number, OMB number, and CMS document identifier, to [Paperwork@cms.hhs.gov](mailto:Paperwork@cms.hhs.gov).

3. Call the Reports Clearance Office at (410) 786-1326.

**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-10287 Medicare Quality of Care Complaint Form

CMS-10540 Quality Improvement Strategy Implementation Plan and Progress Report Form

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