

approved collection; *Title of Information Collection*: Medicaid Program Face-to-Face Requirements for Home Health Services and Supporting Regulations; *Use*: 42 CFR 440.70(f) and (g) requires that physicians (or for medical equipment, authorized non-physician practitioners (NPPs) including nurse practitioners, clinical nurse specialists and physician assistants) document that there was a face-to-face encounter with the Medicaid beneficiary prior to the physician making a certification that home health services are required. The burden associated with this requirement is the time and effort to complete this documentation. The burden also includes writing, typing, or dictating the face-to-face documentation and signing/dating the documentation. *Form Number*: CMS-10609 (OMB control number: 0938-1319); *Frequency*: Occasionally; *Affected Public*: Private sector (business or other for-profits); *Number of Respondents*: 381,148; *Total Annual Responses*: 1,143,443; *Total Annual Hours*: 190,955. (For policy questions regarding this collection contact Alexandra Smilow at 410-786-0790.)

2. *Type of Information Collection Request*: Revision of a currently approved collection; *Title of Information Collection*: Bid Pricing Tool (BPT) for Medicare Advantage (MA) Plans and Prescription Drug Plans (PDP); *Use*: Under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), and implementing regulations at 42 CFR, Medicare Advantage organizations (MAO) and Prescription Drug Plans (PDP) are required to submit an actuarial pricing “bid” for each plan offered to Medicare beneficiaries for approval by the Centers for Medicare & Medicaid Services (CMS).

Medicare Advantage organizations (MAO) and Prescription Drug Plans (PDP) are required to submit an actuarial pricing “bid” for each plan offered to Medicare beneficiaries for approval by CMS. The MAOs and PDPs use the Bid Pricing Tool (BPT) software to develop their actuarial pricing bid. The competitive bidding process defined by the “The Medicare Prescription Drug, Improvement, and Modernization Act” (MMA) applies to both the MA and Part D programs. It is an annual process that encompasses the release of the MA rate book in April, the bid’s that plans submit to CMS in June, and the release of the Part D and RPPO benchmarks, which typically occurs in August. *Form Number*: CMS-10142 (OMB control number: 0938-0944); *Frequency*: Yearly; *Affected Public*:

Private sector (business or other for-profits); *Number of Respondents*: 555; *Total Annual Responses*: 4,995; *Total Annual Hours*: 149,850. (For policy questions regarding this collection contact Rachel Shevland at 410-786-3026.)

Dated: September 18, 2019.

William N. Parham, III,
Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-3387-PN]

Medicare and Medicaid Programs; Application From The Compliance Team (TCT) for Initial CMS Approval of its Diabetes Outpatient Self-Management Training 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 for initial recognition as a national accrediting organization for accrediting entities that wish to furnish diabetes outpatient self-management training services to Medicare beneficiaries.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on October 23, 2019.

ADDRESSES: In commenting, please refer to file code CMS-3387-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-3387-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-3387-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: Christina Mister-Ward, (410) 786-2441. Shannon Freeland, (410) 786-4348. Lillian Williams, (410) 786-8636.

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

Diabetes outpatient self-management training services is defined at section 1861(qq)(1) of the Social Security Act (the Act) as “educational and training services furnished (at such times as the Secretary determines appropriate) to an individual with diabetes by a certified provider (as described in paragraph (2)(A)) in an outpatient setting by an individual or entity who meets the quality standards described in paragraph (2)(B), but only if the physician who is managing the individual’s diabetic condition certifies that such services are needed under a comprehensive plan of care related to the individual’s diabetic condition to ensure therapy compliance or to provide the individual with necessary skills and knowledge (including skills related to the self-administration of injectable drugs) to participate in the management of the individual’s condition.”

In addition, section 1861(qq)(2)(A) of the Act describes a “certified provider” as a physician, or other individual or entity designated by the Secretary of the Department of Health and Human Services (the Secretary), that, in addition to providing diabetes outpatient self-management training services, provides other items or services for which payment may be

made under this title. Section 1861(qq)(2)(B) of the Act further specifies that a physician, or such other individual or entity, must meet the quality standards established by the Secretary, except that the physician or other individual or entity shall be deemed to have met such standards if the physician or other individual or entity meets applicable standards originally established by the National Diabetes Advisory Board and subsequently revised by organizations who participated in the establishment of standards by such Board, or is recognized by an organization that represents individuals (including individuals under this title) with diabetes as meeting standards for furnishing the services.

The statute also permits diabetes outpatient self-management training service programs to be deemed to have met Medicare regulatory quality standards if they are accredited by an organization approved by the Centers for Medicare & Medicaid Services (CMS). A national accrediting organization (AO) must have an agreement in effect with the Secretary and meet the standards and requirements specified in 42 CFR part 410, subpart H, to qualify for deeming authority. Our regulations pertaining to the application procedures to be an approved national accreditation organization for diabetes outpatient self-management training are specified at § 410.142 (CMS process for approving national accreditation organizations). A national accreditation organization applying for deeming authority must provide us with reasonable assurance that the AO requires accredited entities to meet CMS' quality standards, the National Standards for Diabetes Self-Management Education and Support standards, or alternative requirements that meet or exceed our requirements that have been developed by a national accreditation organization and approved by CMS. (See § 410.144 Quality standards for deemed entities.) We may approve and recognize a nonprofit organization with demonstrated experience in representing the interests of individuals with diabetes to accredit entities to furnish training. The national accreditation organization, after being approved and recognized by CMS, may accredit an entity to meet one of the sets of quality standards in § 410.144 (Quality standards for deemed entities).

II. Approval of Accreditation Organizations

Section 1865(a)(2) of the Act and § 410.142 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 CMS with the necessary data for validation.

Section 1865(a)(3) of the Act and § 410.142(d) require that we publish, within 60 days 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. Section 1865(a)(3)(A) of the Act further states, 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 CMS approval of its diabetes outpatient self-management training accreditation program. This notice also solicits public comment on whether TCT's requirements meet or exceed the Medicare conditions for certification for diabetes outpatient self-management training 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 CMS approval of its diabetes outpatient self-management training accreditation program. This application was determined to be complete on July 27, 2019. Under section 1865(a)(2) of the Act and our regulations at § 410.142, our review and evaluation of TCT will be conducted in accordance with our regulations, including:

- The requirements and quality standards TCT uses to accredit entities to furnish training,
- TCT's accreditation process to determine the following:
 - ++ Frequency of accreditation.
 - ++ Copies of accreditation forms, guidelines, and instructions to evaluators.

++ The accreditation review process and the accreditation status decision making process.

++ The procedures used to notify a deemed entity of deficiencies in its diabetes outpatient self-management training program and procedures to monitor the correction of those deficiencies.

++ The procedures used to enforce compliance with the accreditation requirements and standards.

++ Detailed information about the individuals who perform evaluations for the organization.

++ A description of the organization's data management and analysis system for its accreditation activities and decisions, including reports, tables, and other displays generated by that system.

++ A description of the organization's procedures for responding to and investigating complaints against an approved entity, including policies and procedures regarding coordination of these activities with appropriate licensing bodies, ombudsmen programs, and CMS.

++ A description of the organization's policies and procedures for withholding or removing a certificate of accreditation for failure to meet the organization's standards or requirements, and other actions the organization takes in response to noncompliance with its standards and requirements.

++ A description of all types (for example, full or partial) and categories (for example, provisional, conditional, or temporary) of accreditation offered by the organization, the duration of each type and category of accreditation, and a statement identifying the types and categories that will serve as a basis for accreditation if CMS approves the organization.

++ A list of all of the approved entities currently accredited to furnish training and the type, category, and expiration date of the accreditation held by each of them.

++ The name and address of each person with an ownership or control interest in the organization.

++ Documentation that demonstrates its ability to furnish CMS with electronic data in CMS-compatible format.

++ A resource analysis that demonstrates that its staffing, funding, and other resources are adequate to perform the required accreditation activities.

++ A statement acknowledging that, as a condition for approval and recognition by CMS of its accreditation program, it agrees to comply with the requirements set forth in §§ 410.142 through 410.146.

++ Additional information CMS requests to enable it to respond to the organization's request for CMS approval and recognition of its accreditation program to accredit entities to furnish training.

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.

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 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.

Dated: September 6, 2019.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2019-20466 Filed 9-20-19; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2019-D-3805]

The Accreditation Scheme for Conformity Assessment Pilot Program; Draft Guidance for Industry, Accreditation Bodies, Testing Laboratories, and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of the draft guidance entitled “The Accreditation Scheme for Conformity Assessment (ASCA) Pilot Program.” The Pilot Accreditation Scheme for Conformity Assessment Program (hereafter referred to as the ASCA Pilot) is authorized under the Federal Food, Drug, and Cosmetic Act (FD&C Act). In accordance with amendments made to the FD&C Act by the FDA Reauthorization Act of 2017 (FDARA) and as part of the enactment of the Medical Device User Fee Amendments of 2017 (MDUFA IV),

FDA was directed to issue a draft guidance regarding the goals and implementation of the ASCA Pilot. The establishment of the goals, scope, procedures, and a suitable framework for the voluntary ASCA Pilot supports the Agency’s continued efforts to use its scientific resources effectively to protect and promote public health by simplifying certain aspects of premarket review, thereby reducing burdens on the Agency for individual submissions. FDA believes the voluntary ASCA Pilot may further encourage international harmonization of medical device regulation because it incorporates elements, where appropriate, from a well-established set of international conformity assessment practices and standards (*e.g.*, ISO/IEC 17000 series). The voluntary ASCA Pilot does not supplant or alter any other existing statutory or regulatory requirements governing the decision-making process for premarket submissions. This draft guidance is not final nor is it in effect at this time.

DATES: Submit either electronic or written comments on the draft guidance by December 23, 2019 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else’s Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see “Written/Paper Submissions” and “Instructions”).

Written/Paper Submissions

Submit written/paper submissions as follows:

- **Mail/Hand Delivery/Courier (for written/paper submissions):** Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

Instructions: All submissions received must include the Docket No. FDA-2019-D-3805 for “The Accreditation Scheme for Conformity Assessment (ASCA) Pilot Program; Draft Guidance for Industry, Accreditation Bodies, Testing Laboratories, and Food and Drug Administration Staff.” Received comments will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- **Confidential Submissions—**To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the