Survey Provider Enhanced Reporting (CASPER) by the CMS Regional Offices (ROs). The CMS–1880 form is also completed by current Medicare participating portable x-ray supplier during each recertification survey. *Form Numbers:* CMS–1880 (OMB control number: 0938–0027); *Frequency:* Occasionally; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 104; *Total Annual Responses:* 104; *Total Annual Hours:* 26. (For policy questions regarding this collection contact Caroline Gallaher at 410–786–8705.)

Dated: April 21, 2021.

William N. Parham, III,

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

[FR Doc. 2021–08688 Filed 4–26–21; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–3412–PN]

Medicare Program; Application by American Diabetes Association (ADA) for Continued CMS Approval of Its Diabetes Outpatient Self-Management Training Program

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

ACTION: Notice with request for comment.

SUMMARY: This proposed notice acknowledges the receipt of an application from the American Diabetes Association (ADA) for continued recognition as a national accrediting organization (AO) 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, by May 27, 2021.

ADDRESSES: In commenting, refer to file code CMS–3412–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–3412–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–3412–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.

Caroline Gallaher, (410) 786–8705.

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. CMS 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. 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

Diabetes outpatient self-management training services are 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.

Section 1865 of the statute also permits the Secretary to use accrediting bodies to determine whether a provider entity meets Medicare regulatory quality standards, such as those established for diabetes outpatient self-management training service programs. A national AO must be approved by CMS and meet the standards and requirements specified in 42 CFR part 410, subpart H, to qualify for Medicare deeming authority.

Our regulations pertaining to the application procedures for diabetes outpatient self-management training AOs seeking CMS approval are set forth at § 410.142. A national accreditation organization applying for deeming authority must provide CMS with reasonable assurance that it requires the diabetes outpatient self-management training suppliers it accredits to meet the CMS' quality standards, the National Standards for Diabetes Outpatient Self-Management Education and Support (NSDSMES) standards, or an alternative set of standards that meet or exceed our requirements that have been developed by that AO and have been approved by CMS. (See § 410.144.)

Section 410.142(a) states that ''CMS may approve and recognize a nonprofit organization with demonstrated experience in representing the interests of individuals with diabetes to accredit entities to furnish training.'' Therefore, diabetes outpatient self-management training AOs must be not-for-profit organizations. 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.

II. Approval of Accreditation Organizations

Section 1865(a)(2) of the Act and § 410.142 require that our findings from review of a national AO's application 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 the Secretary 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 American Diabetes Association's (ADA's) submission of an application requesting renewal of the CMS approval for its diabetes outpatient self-management training accreditation program. This notice also solicits public comment on whether ADA's requirements meet or exceed the NSDSMES, which are the accreditation standards used for certification of the diabetes outpatient self-management training programs accredited by the ADA, pursuant to § 410.144(b).

III. Evaluation of Deeming Authority Request

The ADA submitted all the necessary materials to enable us to make a determination concerning its request for renewed CMS approval of its diabetes outpatient self-management training accreditation program. This application was determined to be complete on March 1, 2021. Under section 1865(a)(2) of the Act and our regulations at § 410.142, our review and evaluation of the ADA's application will be conducted in accordance with, but not necessarily limited to:

- The requirements and quality standards the ADA uses to accredit entities to furnish diabetes self-outpatient management training.
- The accreditation process used by ADA 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 diabetes outpatient self-management training entity of deficiencies in its diabetes outpatient self-management training program and the procedures used 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 AO.

++ A description of the AO'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 AO'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 AO's policies and procedures for withholding or removing a certificate of accreditation for failure to meet the AO's standards or requirements, and other actions the AO 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 AO, 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's, application.

++ A list of all of the approved entities currently accredited to furnish diabetes outpatient self-management 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 AO.

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

++ A resource analysis that demonstrates that ADA's 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, ADA 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 AO's request for CMS approval and recognition of its diabetes outpatient self-management training accreditation program.

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 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.

The Acting Administrator of the Centers for Medicare & Medicaid Services (CMS), Elizabeth Richter, 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: April 22, 2021.

Lynette Wilson,

Federal Register Liaison, Centers for Medicare & Medicaid Services.

[FR Doc. 2021–08751 Filed 4–26–21; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–D–0320]

Nonclinical Testing of Individualized Antisense Oligonucleotide Drug Products for Severely Debilitating or Life-Threatening Diseases; Draft Guidance for Sponsor-Investigators; 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 a draft guidance for industry entitled ''Nonclinical Testing of Individualized Antisense Oligonucleotide Drug Products for Severely Debilitating or Life-Threatening Diseases.'' FDA is publishing this draft guidance to help sponsor-investigators (hereafter referred to as sponsors) with developing the nonclinical information that FDA recommends to support an investigational new drug application (IND) for certain individualized antisense oligonucleotide (ASO) drug products. ASO drug products that are the focus of this draft guidance are those being developed to treat rapidly progressing, severely debilitating or life-threatening (SDLT) disease attributable to a unique genetic variant or variants that may be amenable to RNA-directed treatment.

DATES: Submit either electronic or written comments on the draft guidance by June 28, 2021 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–2021–D–0320 for ''Nonclinical Testing of Individualized Antisense Oligonucleotide Drug Products for Severely Debilitating or Life-Threatening Diseases.'' 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, 240–402–7500.

- 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.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Ronald Wange, Center for Drug Evaluation and Research (HFD–510), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 3342, Silver Spring, MD 20903, 301–796–1304.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Nonclinical Testing of Individualized Antisense Oligonucleotide Drug Products for Severely Debilitating or Life-Threatening Diseases.'' FDA is publishing this draft guidance, that, when finalized, will help sponsors with developing the nonclinical information that FDA recommends to support an IND for certain individualized ASO drug products. ASO drug products that are the focus of this draft guidance are those being developed to treat a rapidly progressing, SDLT disease attributable