Shortage Workgroup Update. Agenda items are subject to change as priorities dictate.

Public Participation

Written Public Comment: Members of the public are welcome to submit written comments in advance of the meeting. Written comments must be submitted by emailing *nchhstppolicy@cdc.gov* with subject line ''ACET December 2024 Public Comment Registration'' by November 26, 2024.

Oral Public Comment: Individuals who would like to make an oral comment during the public comment period must register by emailing *nchhstppolicy@cdc.gov* with subject line ''ACET December 2024 Public Comment Registration'' by November 26, 2024. The public comment period is on December 4, 2024, at 10:15 a.m., EST.

The Director, Office of Strategic Business Initiatives, Office of the Chief Operating Officer, Centers for Disease Control and Prevention, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Kalwant Smagh,

Director, Office of Strategic Business Initiatives, Office of the Chief Operating Officer, Centers for Disease Control and Prevention.

[FR Doc. 2024–23885 Filed 10–16–24; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Meeting of the Board of Scientific Counselors, Office of Readiness and Response

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice of meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act, the Centers for Disease Control and Prevention (CDC) announces the following meeting for the Board of Scientific Counselors, Office of Readiness and Response (BSC, ORR). This is a virtual meeting and is open to the public, limited only by the number of web conference lines available (500 lines). Time will be available for public comment.

DATES: The meeting will be held on November 20, 2024, from 9:30 a.m. to 4:30 p.m., EST, and November 21, 2024, from 9 a.m. to 3 p.m., EST.

ADDRESSES: Zoom virtual meeting. If you wish to attend the meeting, please register in advance by accessing the link at *https://cdc.zoomgov.com/webinar/register/WN_sIWaL9XVRqWnBKMB2OO2wQ#/registration.* Instructions on accessing the meeting will be provided following registration.

FOR FURTHER INFORMATION CONTACT: Dometa Ouisley, Public Health Analyst, Office of Science and Laboratory Readiness, Office of Readiness and Response, Centers for Disease Control and Prevention, 1600 Clifton Road NE, Mailstop H21–6, Atlanta, Georgia 30329–4027. Telephone: (404) 639–7450; Email: *DOuisley@cdc.gov.*

SUPPLEMENTARY INFORMATION:

Purpose: The Board of Scientific Counselors, Office of Readiness and Response provides advice and guidance to the Secretary, Department of Health and Human Services (HHS); the Assistant Secretary for Health, HHS; the Director, Centers for Disease Control and Prevention (CDC); and the Director, Office of Readiness and Response (ORR), CDC. The Board recommends strategies and goals for readiness and response activities pertaining to programs and research within the agency and the ORR divisions and monitors the overall strategic direction and focus of the ORR divisions and offices. The Board may also perform second-level peer review of applications for grants-in-aid for research and research training activities, cooperative agreements, and research contract proposals relating to the broad areas within the center. For additional information about the Board, please visit *https://www.cdc.gov/orr/scientific-counselors/index.html.*

Matters to be Considered: Agenda topics for Day 1 of the meeting include ORR Updates, ORR Division Director Updates, CDC's Response Readiness Framework, and a CDCReady Demonstration. Agenda topics for Day 2 include Poliovirus Containment Working Group Updates, ORR Science Agenda Working Group Updates, and Health Equity Working Group Updates. Agenda items are subject to change as priorities dictate.

The Director, Office of Strategic Business Initiatives, Office of the Chief Operating Officer, Centers for Disease Control and Prevention, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Kalwant Smagh,

Director, Office of Strategic Business Initiatives, Office of the Chief Operating Officer, Centers for Disease Control and Prevention.

[FR Doc. 2024–23926 Filed 10–16–24; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–3466–PN]

Medicare and Medicaid Programs: Application From the American Association for Accreditation of Ambulatory Surgery Facilities dba QUAD A for Continued CMS-Approval of Its Outpatient Physical Therapy (OPT) 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 American Association for Accreditation of Ambulatory Surgery Facilities, dba QUAD A, for continued recognition as a national accrediting organization for outpatient physical therapy providers that wish to participate in the Medicare or Medicaid programs.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on November 18, 2024.

ADDRESSES: In commenting, refer to file code CMS–3466–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 *https://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–3466–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–3466–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: Caecilia Andrews, (410) 786–2190. Joy Webb, (410) 786–1667.

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 commenter will take actions to harm an 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

A healthcare provider may enter into an agreement with Medicare to participate in the program as a provider of outpatient physical therapy (OPT) provided certain requirements are met. Section 1861(p)(4) of the Social Security Act (the Act), establishes distinct criteria for facilities seeking designation as an OPT. Regulations concerning Medicare provider agreements in general are at 42 CFR part 489 and those pertaining to the survey and certification for Medicare participation of providers and certain types of suppliers are at part 488. The regulations at part 485, subpart H specify the conditions that a provider must meet to participate in the Medicare program as an OPT.

Generally, to enter into an agreement, an OPT must first be certified by a state survey agency (SA) as complying with the conditions or requirements set forth in part 485 of our Medicare regulations. Thereafter, the OPT is subject to regular surveys by an SA to determine whether it continues to meet these requirements. Section 1865(a)(1) of the Act provides that, if a provider entity demonstrates through accreditation by a Centers for Medicare & Medicaid Services (CMS) approved national accrediting organization (AO) that all applicable Medicare conditions are met or exceeded, we may deem that provider entity as having met the requirements. Accreditation by an AO is voluntary and is not required for Medicare participation.

If an AO is recognized by the Secretary of the Department of Health and Human Services as having standards for accreditation that meet or exceed Medicare requirements, any provider entity accredited by the national accrediting body's approved program may be deemed to meet the Medicare conditions. The AO applying for approval of its accreditation program under part 488, subpart A, must provide CMS with reasonable assurance that the AO requires the accredited provider entities to meet requirements that are at least as stringent as the Medicare conditions. Our regulations concerning the approval of AOs are set forth at § 488.5.

The QUAD A's current term of approval for its OPT program expires April 4, 2025.

II. Approval of Deeming Organization

Section 1865(a)(2) of the Act and our regulations at § 488.5 require that our findings concerning review and approval of an 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)(A) of the Act further requires that we publish, within 60 days of receipt of an organization's complete application, 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. 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 QUAD A's request for continued CMS-approval of its OPT accreditation program. This notice also solicits public comment on whether QUAD A's requirements meet or exceed the Medicare conditions for participation (CoPs) for OPTs.

III. Evaluation of Deeming Authority Request

QUAD A submitted all the necessary materials to enable us to make a determination concerning its request for continued CMS-approval of its OPT accreditation program. This application was determined to be complete on September 9, 2024. Under section 1865(a)(2) of the Act and § 488.5, our review and evaluation of QUAD A will be conducted in accordance with, but not necessarily limited to, the following factors:

- The equivalency of QUAD A's standards for OPTs as compared with Medicare's CoPs for OPTs.
- QUAD A'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 QUAD A's processes to those of State agencies, including survey frequency, and the ability to investigate and respond appropriately to complaints against accredited facilities.

++ QUAD A's processes and procedures for monitoring an OPT found out of compliance with QUAD A's program requirements. These monitoring procedures are used only when QUAD A identifies noncompliance. If noncompliance is identified through validation reviews or complaint surveys, the State survey agency monitors corrections as specified at § 488.9(c)(1).

++ QUAD A's capacity to report deficiencies to the surveyed facilities and respond to the facility's plan of correction in a timely manner.

++ QUAD A's capacity to provide CMS with electronic data and reports necessary for the effective validation and assessment of the organization's survey process.

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

++ QUAD A's capacity to adequately fund required surveys.

++ QUAD A's policies with respect to whether surveys are announced or unannounced, to ensure that surveys are unannounced.

++ QUAD A'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.

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

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 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.

The Administrator of the Centers for Medicare & Medicaid Services (CMS), Chiquita Brooks-LaSure, having reviewed and approved this document, authorizes Vanessa Garcia, who is the Federal Register Liaison, to electronically sign this document for purposes of publication in the **Federal Register**.

Vanessa Garcia,

Federal Register Liaison, Centers for Medicare & Medicaid Services.

[FR Doc. 2024–23930 Filed 10–16–24; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–D–4774]

Temporary Policies for Compounding Certain Parenteral Drug Products; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the availability of a final guidance for industry entitled ''Temporary Policies for Compounding Certain Parenteral Drug Products.'' As of October 10, 2024, pursuant to the Public Health Service Act (PHS Act), Department of Health and Human Services (HHS) Secretary Becerra has determined that public health emergencies (PHEs) exist as a result of the consequences of Hurricane Helene in the States of North Carolina, Florida, Georgia, Tennessee, and South Carolina, and as a result of the consequences of Hurricane Milton in the State of Florida. In late September 2024, Hurricane Helene had a devastating impact on one of the largest manufacturers of certain intravenous and peritoneal dialysis solutions in the United States. This guidance describes the FDA's regulatory and enforcement priorities regarding the compounding of certain parenteral drug products by outsourcing facilities and by State-licensed pharmacies and Federal facilities that are not registered with FDA as outsourcing facilities.

DATES: The announcement of the guidance is published in the **Federal Register** on October 17, 2024.

ADDRESSES: You may submit either electronic or written comments on Agency guidances 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–2024–D–4774 for ''Temporary Policies for Compounding Certain Parenteral Drug Products.'' 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)).