- Background
- Online Public Meeting
- Instructions

DATES: The online meeting will be held September 13, 2018 from 1 p.m.–4 p.m., Eastern Time, or until the last public presenter has spoken, whichever occurs first. The public online meeting will be a web-based event available only by remote access. Members of the public who wish to provide public comments should plan to log in to the meeting at the start time listed. Members of the public who register with the NIOSH Docket Office, *niocindocket@cdc.gov,* to attend the public meeting will be provided the login information prior to the meeting.

ADDRESSES: Written comments submitted to the docket must be received by October 15, 2018. Written comments may be submitted by any of the following two methods:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* NIOSH Docket Office, 1090 Tusculum Ave., MS C–34, Cincinnati, Ohio 45226–1998.

FOR FURTHER INFORMATION CONTACT: Doug Daniels, Education and Information Division/NIOSH, 1090 Tusculum Avenue, Cincinnati, OH 45226–1998, telephone (513) 533–8329 (not a toll free number).

SUPPLEMENTARY INFORMATION:

Background: The proposed NIOSH document describes the underlying science and general approach used by NIOSH researchers when conducting high quality, scientifically sound assessments of the health risk associated with workplace hazards. The report focuses on chemical risk assessment practices; however, some of these practices may also benefit assessments of other workplace hazards, such as traumatic injury or work stress. Risk assessments are an important tool for informed decision-making on workplace safeguards; therefore, these assessments have supported NIOSH recommendations on limiting chemical exposures. The information provided by the proposed NIOSH document is intended for NIOSH risk assessors, other scientists, stakeholders, and the public to improve their understanding of the NIOSH risk assessment process.

The purpose of the public review of the draft document is to obtain comments on whether the proposed NIOSH draft document (1) adequately, clearly, and concisely explains NIOSH practices in risk assessment; and (2) demonstrates that its practices are consistent with the current scientific knowledge.

Purpose of Meeting

To discuss and obtain comments on the draft document, *Current Intelligence Bulletin: NIOSH Practices in Occupational Risk Assessment.* Special emphasis will be placed on discussion of the following questions for reviewers:

(1) Are the methods presented in the proposed NIOSH document consistent with the current scientific knowledge of toxicology, epidemiology, industrial hygiene, and risk assessment? If not, provide specific information and references that should be considered.

(2) Is there additional scientific information related to the issues of the proposed NIOSH document that should be considered for inclusion? If so, provide information and specify references for consideration. Is there any discussion in the document that should be omitted?

(3) Is information in the proposed NIOSH document explained in a clear and transparent manner? If not, specify (section, page, and line number) where clarification is needed.

Online Public Meeting

The meeting is open to the public, limited only by the number of logins available. The Adobe Connect license accommodates approximately 500 people. In addition, there will be an audio conference for those who cannot log in through a computer. There is no registration fee to attend this public online meeting. However, those wishing to attend are encouraged to register via email to NIOSH Docket Office *niocindocket@cdc.gov* by September 6, 2018. Registrants will be provided with the public meeting login information prior to the meeting. Individuals wishing to speak during the meeting may sign up when registering. Those who have not signed up to present in advance may be allowed to present at the meeting if time allows. Persons wanting to provide oral comments will be permitted up to 20 minutes. If additional time becomes available, presenters will be notified. Oral comments given at the meeting must also be submitted to the docket in writing in order to be considered by the Agency. Priority for attendance will be given to those providing oral comments. Other requests to attend the meeting will then be accommodated on a first-come basis. Unreserved attendees will be admitted as login space allows.

Instructions: All material submitted to the Agency should reference the agency name and docket number [CDC–2018–0060; NIOSH–316]. Each person making a comment will be asked to give his or her name and affiliation, and all comments (including their name and affiliation) will be posted without change to *https://www.regulations.gov.* All information received in response to this notice will be available for public examination and copying at the NIOSH Docket Office, Room 155, 1150 Tusculum Parkway, Cincinnati, Ohio 45226–1998.

Dated: July 23, 2018.

Frank J. Hearl,

Chief of Staff, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention.

[FR Doc. 2018–15967 Filed 7–25–18; 8:45 am]

BILLING CODE 4163–19–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–3362–PN]

Medicare and Medicaid Programs: Application From the Accreditation Association for Ambulatory Health Care, Inc. (AAAHC) for Continued Approval of Its Ambulatory Surgical Center Accreditation Program

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

ACTION: Notice with request for comment.

SUMMARY: This proposed notice acknowledges the receipt of an application from the Accreditation Association for Ambulatory Health Care, Inc. (AAAHC) for continued recognition as a national accrediting organization (AO) for Ambulatory Surgical Centers (ASCs) 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 August 27, 2018.

ADDRESSES: In commenting, refer to file code CMS–3362–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–3362–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–3362–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: Erin McCoy, (410) 786–2337, Monda Shaver, (410) 786–3410, or Marie Vasbinder, (410) 786–8665.

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

Under the Medicare program, eligible beneficiaries may receive covered services from an Ambulatory Surgical Center (ASC) provided certain requirements are met. Section 1832(a)(2)(F)(i) of the Social Security Act (the Act) establishes distinct criteria for facilities seeking designation as an ASC. Regulations concerning provider agreements are at 42 CFR part 489 and those pertaining to activities relating to the survey and certification of facilities are at 42 CFR part 488. The regulations at 42 CFR part 416 specify the conditions that an ASC must meet in order to participate in the Medicare program, the scope of covered services, and the conditions for Medicare payment for ASCs.

Generally, to enter into an agreement, an ASC must first be certified by a State survey agency as complying with the conditions or requirements set forth in part 416 of our Medicare regulations. Thereafter, the ASC is subject to regular surveys by a State survey agency 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 those provider entities 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. An 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 Accreditation Association for Ambulatory Health Care, Inc.'s (AAAHC's) current term of approval for its ASC program expires December 20, 2018.

II. Provisions of the Proposed Notice

A. Approval of Deeming Organizations

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 identifying the national accrediting body making the request, describing the nature of the request, and providing 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 AAAHC's request for continued CMS-approval of its ASC accreditation program. This notice also solicits public comment on whether AAAHC's requirements meet or exceed the Medicare conditions for coverage (CfCs) for ASCs.

B. Evaluation of Deeming Authority Request

AAAHC submitted all the necessary materials to enable us to make a determination concerning its request for continued CMS-approval of its ASC accreditation program. This application was determined to be complete on May 24, 2018. Under section 1865(a)(2) of the Act and our regulations at § 488.5, our review and evaluation of AAAHC will be conducted in accordance with, but not necessarily limited to, the following factors:

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

++ AAAHC's processes and procedures for monitoring an ASC found out of compliance with AAAHC's program requirements. These monitoring procedures are used only when AAAHC 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).

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

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

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

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

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

++ AAAHC'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).

C. Notice Upon Completion of Evaluation

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

III. 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.*).

IV. 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.

Dated: July 20, 2018.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2018–15951 Filed 7–23–18; 4:15 pm]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Proposed Projects:

Title: National Youth in Transition Database (NYTD) and Youth Outcomes Survey.

OMB No.: 0970–0340.

Description: The John H. Chafee Foster Care Program for Successful Transition to Adulthood (42 U.S.C. 677, as amended by Pub. L. 115–123, the Family First Prevention Services Act within Division E, Title VII of the Bipartisan Budget Act of 2018) requires State child welfare agencies to collect and report to the Administration for Children and Families (ACF) data on the characteristics of youth receiving independent living services and information regarding their outcomes. The regulation implementing the National Youth in Transition Database (NYTD), listed in 45 CFR 1356.80, contains standard data collection and reporting requirements for States to meet the law's requirements. ACF uses the information collected under the regulation to track independent living services, assess the collective outcomes of youth, and assess performance with regard to those outcomes, consistent with the law's mandate.

Respondents: State agencies (including agencies of the District of Columbia, Puerto Rico and the U.S. Virgin Islands) that administer the John H. Chafee Foster Care Program for Successful Transition to Adulthood.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Youth Outcome Survey	21,064	1	0.50	10,529
Data File	53	2	1,849	195,994

Estimated Total Annual Burden Hours: 206,253.

In compliance with the requirements of the Paperwork Reduction Act of 1995 (Pub. L. 104–13, 44 U.S.C. Chap 35), the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 330 C Street SW, Washington, DC 20201. Attn: ACF Reports Clearance Officer. Email address: *infocollection@acf.hhs.gov.* All requests should be identified by the title of the information collection.

The Department specifically requests comments on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2018–15989 Filed 7–25–18; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–1011]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Permanent Discontinuation or Interruption in Manufacturing of Certain Drug and Biological Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by August 27, 2018.