DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Docket No. CDC–2015–0049]

Notice of Availability of a Revised Environmental Assessment for HHS/CDC Lawrenceville Campus Proposed Improvements 2015–2025, Lawrenceville, Georgia

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

ACTION: Notice of availability and request for comment.

SUMMARY: The Centers for Disease Control and Prevention (CDC), within the Department of Health and Human Services (HHS), announces the availability and opportunity for public review and comment of a revised Environmental Assessment (EA) for the HHS/CDC Lawrenceville Campus Proposed Improvements 2015–2025 on the HHS/CDC Lawrenceville Campus, Lawrenceville, Georgia. The revised EA has been prepared in accordance with the National Environmental Policy Act of 1969 (NEPA), as amended (42 U.S.C. 4321 et seq.), the Council on Environmental Quality (CEQ) implementing regulations (40 CFR 1500–1508) and the HHS General Administration Manual (GAM) Part 30 Environmental Procedures, dated February 25, 2000.

DATES: Written comments must be received by October 23, 2017.

ADDRESSES: You may submit comments, identified by Docket No. CDC–2015–0049 by any of the following methods:

• Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments.

• Mail: Comments submitted by mail should be sent to Stephen Klim, RA, LEED Green Associate, Office of Safety, Security, and Asset Management, Centers for Disease Control and Prevention, 1600 Clifton Road NE., MS–K96, Atlanta, Georgia 30329, Telephone: (770) 488–8009.

Instructions: All submissions received must include the agency name and Docket Number. All relevant comments received will be posted without change to http://regulations.gov, including any personal information provided. For access to the docket to read background documents or comments received, go to http://www.regulations.gov.

Hard copies of the revised EA are available for review at the following locations:

- Gwinnett County Public Library, Lawrenceville Branch, 1001 Lawrenceville Hwy, Lawrenceville, GA 30046, Telephone: (770) 978–5154.
- Gwinnett County Public Library, Five Forks Branch, 2780 Five Forks Trickum Road, Lawrenceville, GA 30044–5865, Telephone: (770) 978–5154.
- Gwinnett County Public Library, Grayson Branch, 700 Grayson Parkway, Grayson, GA 30017–1208, Telephone: (770) 978–5154.

FOR FURTHER INFORMATION CONTACT: Stephen Klim, RA, Office of Safety, Security, and Asset Management, Centers for Disease Control and Prevention, 1600 Clifton Road NE., MS–K96, Atlanta, Georgia 30329, Telephone: (770)488–8009.

SUPPLEMENTARY INFORMATION: On February 16, 2016 CDC published a Notice of Availability for the Final Environmental Assessment (2016 Final EA) and Finding of No Significant Impact (FONSI) for the HHS/CDC’s Lawrenceville Campus Proposed Improvements 2015–2025 (81 FR 7800). The proposed improvements identified in the 2016 Final EA included (1) building demolition; (2) new building construction, including an approximately 12,000 gross square feet (gsf) Science Support Building, a new Transshipping and Receiving Area at approximately 2,500 gsf and two new Office Support Buildings at approximately 8,000 gsf and 6,000 gsf; (3) expansion and relocation of parking on campus; and (4) the creation of an additional point of access to the campus and pedestrian improvements. The 2016 Final EA concluded that no significant impacts to the human or natural environment would result and HHS/CDC issued a FONSI.

Since completion of the 2016 Final EA and FONSI, HHS/CDC proposed changes to the Proposed Action. HHS/CDC has revised the EA to include the installation of a photovoltaic system within the northern portion of the campus. The photovoltaic system would consist of a 249.9-kilowatt (KW) ground-mounted solar array covering an area of approximately 41,750 sf (0.99 acre). The proposed photovoltaic system would provide the Lawrenceville Campus with a renewable energy source in order to comply with federal renewable energy mandates.

The revised EA evaluates the potential environmental impacts of the proposed photovoltaic system, along with the proposed improvements identified in the 2016 Final EA. Potential impacts of the No Build and the Build Alternative are evaluated on the following resource categories: Socioeconomics; land use; zoning; public policy; community facilities; transportation; air quality; noise; cultural resources; urban design and visual resources; natural resources; utilities; waste; and greenhouse gases and sustainability.

Dated: September 18, 2017.

Lauren Hoffman,
Acting Executive Secretary, Centers for Disease Control and Prevention.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–3343–FN]

Medicare and Medicaid Programs; Continued Approval of the American Osteopathic Association/Healthcare Facilities Accreditation Program’s (AOA/HFAP’s) Ambulatory Surgical Center Accreditation Program

AGENCY: Centers for Medicare & Medicaid Services, HHS.

ACTION: Final notice.

SUMMARY: This final notice announces our decision to approve the American Osteopathic Association/Healthcare Facilities Accreditation Program (AOA/HFAP) for continued recognition as a national accrediting organization for ambulatory surgical centers (ASCs) that wish to participate in the Medicare or Medicaid programs.

DATES: This final notice is effective September 22, 2017 through September 22, 2023.

FOR FURTHER INFORMATION CONTACT: Monda Shaver, (410) 786–3410, Erin McCoy, (410) 786–2337, or Patricia Chmielewski, (410) 786–6899.

SUPPLEMENTARY INFORMATION:

I. Background

Under the Medicare program, eligible beneficiaries may receive covered services in an ambulatory surgical center (ASC) provided certain requirements are met. Sections
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 as complying with the conditions set forth in Part 416 and recommended to the Centers of Medicare & Medicaid Services (CMS) for participation by a state survey agency. Thereafter, the ASC is subject to periodic surveys by a state survey agency to determine whether it continues to meet these conditions. However, there is an alternative to certification surveys by state agencies. Accreditation by a nationally recognized Medicare accreditation program approved by CMS may substitute for both initial and ongoing state review.

Section 1865(a)(1) of the Act provides that, if the Secretary of the Department of Health and Human Services (the Secretary) finds that accreditation of a provider entity by an approved national accrediting organization meets or exceeds all applicable Medicare conditions, we may treat the provider entity as having met those conditions, that is, we may “deem” the provider entity to be in compliance. Accreditation by an accrediting organization is voluntary and is not required for Medicare participation.

Part 488, subpart A, implements the provisions of section 1865 of the Act and requires that a national accrediting organization applying for approval of its Medicare accreditation program to provide CMS with reasonable assurance that the accrediting organization requires its accredited provider entities to meet requirements that are at least as stringent as the Medicare conditions. Our regulations concerning the approval of accrediting organizations are set forth at § 488.5.

II. Application Approval Process

Section 1865(a)(3)(A) of the Act provides a statutory timetable to ensure that our review of applications for CMS approval of an accreditation program is conducted in a timely manner. The Act provides us 210 days after the date of receipt of a complete application, with any documentation necessary to make the determination, to complete our survey activities and application process. Within 60 days after receiving a complete application, we must publish a notice in the Federal Register that identifies the national accrediting body making the request, describes the request, and provides no less than a 30-day public comment period. At the end of the 210-day period, we must publish a notice in the Federal Register approving or denying the application.

III. Provisions of the Proposed Notice

On June 13, 2017, we published a proposed notice (82 FR 27067) in the Federal Register, announcing AOA/HFAP’s request for continued approval of its Medicare ASC accreditation program. In the proposed notice, we detailed our evaluation criteria. Under section 1865(a)(2) of the Act and in our regulations at § 488.5, we conducted a review of AOA/HFAP’s Medicare ASC accreditation renewal application in accordance with the criteria specified by our regulations, which include, but are not limited to the following:

- An onsite administrative review of AOA/HFAP’s: (1) Corporate policies; (2) financial and human resources available to accomplish the proposed surveys; (3) procedures for training, monitoring and evaluation of its ASC surveyors; (4) ability to investigate and respond appropriately to complaints against accredited ASCs; and (5) survey review and decision-making process for accreditation.
- The comparison of AOA/HFAP’s Medicare accreditation program standards to our current Medicare ASC condition of coverage (CIC’s).
- A documentation review of AOA/HFAP’s survey process to:
  - Determine the composition of the survey team, surveyor qualifications, and AOA/HFAP’s ability to provide continuing surveyor training.
  - Compare AOA/HFAP’s processes to those we require of state survey agencies, including periodic resurvey and the ability to investigate and respond appropriately to complaints against accredited ASCs.
  - Evaluate AOA/HFAP’s procedures for monitoring ASCs to determine if it is out of compliance with AOA/HFAP’s program requirements. (This pertains only to monitoring procedures when AOA/HFAP identifies non-compliance. If noncompliance is identified by a state survey agency through a validation survey, the state survey agency monitors corrections as specified at § 488.9(c).)
  - Assess AOA/HFAP’s ability to report deficiencies to the surveyed ASC and respond to the ASCs plan of corrections in a timely manner.
  - Establish AOA/HFAP’s ability to provide CMS with electronic data and reports necessary for effective validation and assessment of the organization’s survey process.
- Determine the adequacy of AOA/HFAP’s staff and other resources.
- Confirm AOA/HFAP’s ability to provide adequate funding for performing required surveys.
- Confirm AOA/HFAP’s policies with respect to surveys being unannounced.
- Obtain AOA/HFAP’s agreement to provide CMS with a copy of the most current accreditation survey, along with any other information related to the survey as we may require, including corrective action plans.

In accordance with section 1865(a)(3)(A) of the Act, the June 13, 2017 proposed notice also solicited public comments regarding whether AOA/HFAP’s requirements met or exceeded the Medicare CICs for ASCs. We received 2 comments in response to our proposed notice. All of the comments received expressed unanimous support for AOA/HFAP’s Medicare accreditation program.

IV. Provisions of the Final Notice

A. Differences Between AOA/HFAP’s Standards and Requirements for Accreditation and Medicare Conditions and Survey Requirements

We compared AOA/HFAP’s ASC accreditation program requirements and survey process with the Medicare CICs at 42 CFR part 416, and the survey and certification process requirements of Parts 488 and 489. Our review and evaluation of AOA/HFAP’s ASC application, which were conducted as described in section III of this final notice, yielded the following areas where, as of the date of this notice, AOA/HFAP has revised its standards and certification processes in order to meet the requirements at:

- Section 416.2, to ensure its standards appropriately reference § 416.2 and Part 416 subparts B and C.
- Section 416.25, to ensure its standards require facilities meet the definition at § 416.2.
- Section 416.41(b)(3)(i), to ensure its standards appropriately reference § 416.41(b)(2).
- Section 416.41(b)(3)(ii), to ensure its standards appropriately reference § 416.41(b)(2).
- Section 416.42(b)(2), to ensure its standards appropriately reference § 416.42(c).
- Section 416.49(b)(2), to ensure its standards appropriately reference § 416.49(c).
- Section 416.50(a), to ensure its standards appropriately reference § 416.50.
DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

Activity 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 November 21, 2017.

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:


2. Email your request, including your address, phone number, OMB number, and CMS document identifier, to Paperwork@cms.hhs.gov.

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

FOR FURTHER INFORMATION CONTACT: William 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–R–185 Granting and Withdrawal of Deeming Authority to Private Nonprofit Accreditation Organizations and CLIA Exemption under State Laboratory Programs

CMS–718–721 Business Proposal Forms for Quality Improvement Organizations (QIOs)

CMS–10123–10124 Fast Track Appeals Notices: NOMNC/DENC

CMS–10142 Bid Pricing Tool (BPT) for Medicare Advantage (MA) Plans and Prescription Drug Plans (PDP)


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 provide information to a third party. Section 3506(c)(2)(A) of the PRA requires federal agencies to publish a 60-day notice in the Federal Register concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice.

Information Collection

1. Type of Information Collection Request: Title of Information Collection: Granting and Withdrawal of Deeming Authority to Private Nonprofit Accreditation Organizations and CLIA Exemption Under State Laboratory Programs: Use: The information required is necessary to determine whether a private accreditation organization/State licensure program standards and accreditation/licensure process is at least equal to or more stringent than those of the Clinical Laboratory Improvement Amendments of 1988 (CLIA). If an accreditation organization is approved, the laboratories that it...