have a serious or immediate impact on patient care.

G. Subpart R—Enforcement Procedures

The COLA meets the requirements of subpart R to the extent that it applies to accreditation organizations. The COLA policy sets forth the actions the organization takes when laboratories it accredits do not comply with its requirements and standards for accreditation. When appropriate, the COLA will deny, suspend, or revoke accreditation in a laboratory accredited by the COLA and report that action to us within 30 days. The COLA also provides an appeals process for laboratories that have had accreditation denied, suspended, or revoked.

We have determined that the COLA’s laboratory enforcement and appeal policies are equal to or more stringent than the requirements of part 493 subpart R as they apply to accreditation organizations.

IV. Federal Validation Inspections and Continuing Oversight

The federal validation inspections of laboratories accredited by the COLA may be conducted on a representative sample basis or in response to substantial allegations of noncompliance (that is, complaint inspections). The outcome of those validation inspections, performed by CMS or our agents, or the state survey agencies, will be our principal means for verifying that the laboratories accredited by the COLA remain in compliance with CLIA requirements. This federal monitoring is an ongoing process.

V. Removal of Approval as an Accrediting Organization

Our regulations provide that we may rescind the approval of an accreditation organization, such as that of the COLA, for cause, before the end of the effective date of approval. If we determine that the COLA has failed to adopt, maintain and enforce requirements that are equal to, or more stringent than, the CLIA requirements, or that systemic problems exist in its monitoring, inspection or enforcement processes, we may impose a probationary period, not to exceed 1 year, in which the COLA would be allowed to address any identified issues. Should the COLA be unable to address the identified issues within that timeframe, CMS may, in accordance with the applicable regulations, revoke COLA’s deeming authority under CLIA.

Should circumstances result in our withdrawal of the COLA’s approval, we will publish a notice in the Federal Register explaining the basis for removing its approval.

VI. Collection of Information Requirements

This notice does not impose any information collection and record keeping requirements subject to the Paperwork Reduction Act (PRA). Consequently, it does not need to be reviewed by the Office of Management and Budget (OMB) under the authority of the PRA. The requirements associated with the accreditation process for clinical laboratories under the CLIA program, codified in 42 CFR part 493 subpart E, are currently approved by OMB under OMB approval number 0938–0686.

VII. Executive Order 12866 Statement

In accordance with the provisions of Executive Order 12866, this notice was not reviewed by the Office of Management and Budget.

Authority: Section 353 of the Public Health Service Act (42 U.S.C. 263a).

Dated: February 8, 2013.

Marilyn Tavenner,

Acting Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2013–09397 Filed 2–21–13; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–3280–PN]

Medicare and Medicaid Programs; Application From the Center for Improvement in Healthcare Quality (CIHQ) for CMS-Approval of Its Hospital Accreditation Program

AGENCY: Centers for Medicare & Medicaid Services, HHS.

ACTION: Proposed notice.

SUMMARY: This proposed notice with comment period acknowledges the receipt of an application from the Center for Improvement in Healthcare Quality (CIHQ) for recognition as a national accrediting organization for hospitals 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 March 25, 2013.

ADDRESSES: In commenting, refer to file code (CMS–3280–PN). Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (choose only one of the ways listed):

1. Electronically. You may submit electronic comments on specific issues in 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–3280–PN, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1800. 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–3280–PN, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1800.

4. By hand or courier. Alternatively, you may deliver (by hand or courier) your written ONLY to the following addresses.


(Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without Federal Government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

b. For delivery in Baltimore, MD—Centers for Medicare & Medicaid Services, Department of Health and Human Services, 7500 Security Boulevard, Baltimore, MD 21244–1850.

If you intend to deliver your comments to the Baltimore address, call telephone number (410) 786–9994 in advance to schedule your arrival with one of our staff members.

Comments erroneously mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period. For information on viewing public comments, see the beginning of the SUPPLEMENTARY INFORMATION section.

FOR FURTHER INFORMATION CONTACT: Cindy Melanson, (410) 786–0310; Patricia Chmielewski, (410) 786–6899; Monda Shaver, (410) 786–3410.
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 Web site as soon as possible after they have been received: http://www.regulations.gov. Follow the search instructions on that Web site to view public comments.

Comments received timely will also be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1–800–743–3951.

I. Background

Under the Medicare program, eligible beneficiaries may receive covered services in a hospital provided certain requirements are met. Section 1861(e) of the Social Security Act (the Act), establishes criteria for facilities seeking designation as a hospital. Regulations concerning provider agreements are located at 42 CFR part 489 and those pertaining to activities relating to the survey and certification of facilities are located at 42 CFR part 488. The regulations at 42 CFR part 482, specify the conditions that a hospital must meet to participate in the Medicare programs, the scope of covered services, and the conditions for Medicare payment for hospitals.

Generally, to enter into an agreement, a hospital must first be certified by a State survey agency as complying with the conditions or requirements set forth in part 482 of our regulations. Thereafter, the hospital 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 an approved national accrediting organization that all applicable Medicare conditions are met or exceeded, we will deem those provider entities as having met the requirements. Accreditation by an accrediting organization is voluntary and is not required for Medicare participation.

If an accrediting organization is recognized by the Secretary as having standards for accreditation that meet or exceed Medicare requirements, any provider entity accredited by the national accrediting body’s approved program would be deemed to meet the Medicare conditions. A national accrediting organization applying for approval of its accreditation program under part 488, subpart A, must provide us with reasonable assurance that the accrediting organization requires the 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 § 488.4 and § 488.8(d)(3). The regulations at § 488.8(d)(3) require an accredited organization to reapply for continued approval of its accreditation program every 6 years or sooner as determined by CMS.

II. Approval of Deeming Organizations

Section 1865(a)(2) of the Act and our regulations at § 488.8(a) require that our findings concerning review and approval of a national accrediting organization’s requirements, consider among other factors, the applying accrediting organization’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 completed application to publish a notice of approval or denial of the application.

The purpose of this proposed notice is to inform the public of CIHQ’s request for approval of its hospital accreditation program. This notice also solicits public comment on whether CIHQ’s requirements meet or exceed Medicare’s conditions of participation for hospitals.

III. Evaluation of Deeming Authority Request

CIHQ submitted all the necessary materials to enable us to make a determination concerning its request for approval of its hospital accreditation program. This application was determined to be complete on January 4, 2013. Under section 1865(a)(2) of the Act and our regulations at § 488.8 (Federal review of accrediting organizations), our review and evaluation of CIHQ will be conducted in accordance with, but not necessarily limited to, the following factors:

• The equivalency of CIHQ’s standards for a hospital as compared with CMS’ hospital conditions of participation.
• CIHQ’s survey process to determine the following:
  + CIHQ’s composition of the survey team, surveyor qualifications, and the ability of the organization to provide continuing surveyor training.
  + CIHQ’s processes compared to those of State agencies, including survey frequency, and the ability to investigate and respond appropriately to complaints against accredited facilities.
  + CIHQ’s processes and procedures for monitoring a hospital that is out of compliance with CIHQ’s program requirements. These monitoring procedures are used only when CIHQ identifies noncompliance. If noncompliance is identified through validation reviews or complaint surveys, the State survey agency monitors corrections as specified at § 488.7(d).
  + CIHQ’s capacity to report deficiencies to the surveyed facilities and respond to the facility’s plan of correction in a timely manner.
  + CIHQ’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 CIHQ’s staff and other resources, and its financial viability.
  + CIHQ’s capacity to adequately fund required surveys.
  + CIHQ’s policies with respect to whether surveys are announced or unannounced.
  + CIHQ’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 and recordkeeping requirements. Consequently, it need not be reviewed by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995.

V. Response to Public Comments

Because of the large number of public comments we normally receive on
DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–7027–N]

Medicare, Medicaid, and Children’s Health Insurance Programs; Meeting of the Advisory Panel on Outreach and Education (APOE), March 27, 2013

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

ACTION: Notice of meeting.

SUMMARY: This notice announces a meeting of the Advisory Panel on Outreach and Education (APOE) (the Panel) in accordance with the Federal Advisory Committee Act. The Panel advises and makes recommendations to the Secretary of Health and Human Services and the Administrator of the Centers for Medicare & Medicaid Services on opportunities to enhance the effectiveness of consumer education strategies concerning Medicare, Medicaid, and the Children’s Health Insurance Program (CHIP). This meeting is open to the public.

DATES: Meeting Date: Wednesday, March 27, 2013, 8:30 a.m. to 4:00 p.m. Eastern Daylight Time (EDT).

Deadline for Meeting Registration, Presentations, and Written Comments: Wednesday, March 13, 2013, 5:00 p.m., EDT.

Deadline for Requesting Special Accommodations: Wednesday, March 13, 2013, 5:00 p.m., EDT.

ADDRESSES: Meeting Location: The Embassy Row Hotel, 2015 Massachusetts Avenue NW., Washington, DC 20036.


Registration: The meeting is open to the public, but attendance is limited to the space available. Persons wishing to attend this meeting must register at the Web site http://events.SignUp4.com/APOEMAR2013MTG or by contacting the DFO at the address listed in the ADDRESSES section of this notice by telephone at number listed in the FOR FURTHER INFORMATION CONTACT section of this notice, by the date listed in the DATES section of this notice. Individuals requiring sign language interpretation or other special accommodations should contact the DFO at the address listed in the ADDRESSES section of this notice by telephone at number listed in the FOR FURTHER INFORMATION CONTACT section of this notice, by the date listed in the DATES section of this notice.


SUPPLEMENTARY INFORMATION: In accordance with section 10(a) of the Federal Advisory Committee Act (FACA), this notice announces a meeting of the Advisory Panel on Outreach and Education (APOE) (the Panel). Section 9(a)(2) of the Federal Advisory Committee Act authorizes the Secretary of Health and Human Services (the Secretary) to establish an advisory panel if the Secretary determines that the panel is “in the public interest in connection with the performance of duties imposed * * * by law.” Such duties are imposed by section 1804 of the Social Security Act (the Act), requiring the Secretary to provide informational materials to Medicare beneficiaries about the Medicare program, and section 1851(d) of the Act, requiring the Secretary to provide for “activities * * * to broadly disseminate information to Medicare beneficiaries * * * on the coverage options provided under [Medicare Advantage] in order to promote an active, informed selection among such options.”

The Panel is also authorized by section 1114(f) of the Act (42 U.S.C. 1314(f)) and section 222 of the Public Health Service Act (42 U.S.C. 217a). The Secretary signed the charter establishing this Panel on January 21, 1999 (64 FR 7899, February 17, 1999) and approved the renewal of the charter on January 21, 2011 (76 FR 11782, March 3, 2011).

Pursuant to the amended charter, the Panel advises and makes recommendations to the Secretary of Health and Human Services and the Administrator of the Centers for Medicare & Medicaid Services (CMS) concerning optimal strategies for the following:

- Developing and implementing education and outreach programs for individuals enrolled in, or eligible for, Medicare, Medicaid, and the Children’s Health Insurance Program (CHIP).
- Enhancing the federal governments effectiveness in informing Medicare, Medicaid, and CHIP consumers, providers and stakeholders pursuant to education and outreach programs of issues regarding these and other health coverage programs, including the appropriate use of public-private partnerships to leverage the resources of the private sector in educating beneficiaries, providers and stakeholders.
- Expanding outreach to vulnerable and underserved communities, including racial and ethnic minorities, in the context of Medicare, Medicaid, and CHIP education programs.
- Assembling and sharing an information base of “best practices” for helping consumers evaluate health plan options.
- Building and leveraging existing community infrastructures for information, counseling, and assistance.
- Drawing the program link between outreach and education, promoting consumer understanding of health care coverage choices and facilitating consumer selection/enrollment, which in turn support the overarching goal of improved access to quality care, including prevention services, envisioned under health care reform.

The current members of the Panel are: Samantha Artiga, Principal Policy Analyst, Kaiser Family Foundation; Joseph Baker, President, Medicare Rights Center; Philip Bergquist, Manager, Health Center Operations, CHIPRA Outreach & Enrollment Project and Director, Michigan Primary Care Association; Marjorie Cadogan, Deputy Commissioner, Department of Social Services; Jonathan Dauphine, Senior Vice President, AARP;