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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-3280-FN]

Medicare and Medicaid Programs; Initial Approval of Center for Improvement in Healthcare Quality's (CIHQ's) Hospital Accreditation Program

AGENCY: Centers for Medicare and Medicaid Services, HHS.

ACTION: Final notice.

SUMMARY: This final notice announces our decision to approve the Center for Improvement in Healthcare Quality (CIHQ) as a national accrediting organization for hospitals that wish to participate in the Medicare or Medicaid programs.

DATES: This final notice is effective July 26, 2013 through July 26, 2017.

FOR FURTHER INFORMATION CONTACT: Cindy Melanson, (410) 786-0310. Monda Shaver, (410) 786-3410. Patricia Chmielewski, (410) 786-6899.

SUPPLEMENTARY INFORMATION:

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 distinct criteria for facilities seeking designation as a hospital. 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 482 specify the conditions that a hospital must meet to participate in the Medicare program, 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. Thereafter, the hospital is subject to regular surveys by a State survey agency to determine whether it continues to meet these requirements. However, there is an alternative to surveys by State agencies. Certification by a nationally recognized accreditation program can substitute for ongoing State review.

Section 1865(a)(1) of the Act provides that, if a provider entity demonstrates through accreditation by an approved national accrediting organization (AO) that all applicable Medicare conditions are met or exceeded, we will 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 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 have met the Medicare conditions. A national 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 § 488.4 and § 488.8(d)(3). The regulations at § 488.8(d)(3) require AOs to reapply for continued approval of their accreditation program every 6 years, or sooner, as determined by CMS.

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 February 22, 2013, we published a proposed notice in the **Federal Register** (78 FR 12325) announcing CIHQ's request for approval of its hospital accreditation program. In the proposed notice, we detailed our evaluation criteria. Under section 1865(a)(2) of the Act, and in our regulations at § 488.4 and § 488.8, we conducted a review of CIHQ's application in accordance with the criteria specified by our regulations,

which include, but are not limited to, the following:

- An onsite administrative review of CIHQ's: (1) Corporate policies; (2) financial and human resources available to accomplish the proposed surveys; (3) procedures for training, monitoring, and evaluation of its surveyors; (4) ability to investigate and respond appropriately to complaints against accredited facilities; and, (5) survey review and decision-making process for accreditation.

- The comparison of CIHQ's accreditation to our current Medicare hospital conditions of participation.

- A documentation review of CIHQ's survey process to determine the following:

- ++ Determine the composition of the survey team, surveyor qualifications, and CIHQ's ability to provide continuing surveyor training.

- ++ Compare CIHQ's processes to those of State survey agencies, including survey frequency, and the ability to investigate and respond appropriately to complaints against accredited facilities.

- ++ Evaluate CIHQ's procedures for monitoring hospitals out of compliance with CIHQ's program requirements. The monitoring procedures are used only when CIHQ identifies noncompliance. If noncompliance is identified through validation reviews, the State survey agency monitors corrections as specified at § 488.7(d).

- ++ Assess CIHQ's ability to report deficiencies to the surveyed facilities and respond to the facility's plan of correction in a timely manner.

- ++ Establish CIHQ'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 staff and other resources.

- ++ Confirm CIHQ's ability to provide adequate funding for performing required surveys.

- ++ Confirm CIHQ's policies with respect to whether surveys are announced or unannounced.

- ++ Obtain 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 we may require, including corrective action plans.

In accordance with section 1865(a)(3)(A) of the Act, the February 22, 2013 proposed notice also solicited public comments regarding whether CIHQ's requirements met or exceeded the Medicare conditions of participation for hospitals. We received 56 comments in response to our proposed notice. The commenters expressed unanimous support for CIHQ's hospital

accreditation program. In addition, the commenters stated CIHQ's standards are closely aligned with the hospital conditions of participation, thus allowing hospitals to be in compliance with the Medicare requirements.

IV. Provisions of the Final Notice

A. Differences Between CIHQ's Standards and Requirements for Accreditation and Medicare's Conditions and Survey Requirements

We compared CIHQ's hospital requirements and survey process with the Medicare conditions of participation and survey process as outlined in the State Operations Manual (SOM). Our review and evaluation of CIHQ's hospital application, which were conducted as described in section III of this final notice, yielded the following:

- To meet the requirements at § 482.13(a)(2), CIHQ revised its standards to address the hospital's responsibility to provide a process for prompt resolution of patient grievances.
- To meet the requirements at § 482.13(b)(2), CIHQ revised its standards to address the role of the patient's representative (as allowed under State law).
- To meet the requirements at § 482.13(b)(3), CIHQ revised its standards to include the requirements at § 489.100, § 489.102, and § 489.104 regarding advance directives.
- To meet the requirements at § 482.13(d)(2), CIHQ revised its standards to ensure that hospitals have a responsibility to meet patient requests for access to information as quickly as its record keeping system permits.
- To meet the requirements at § 482.13(e)(4)(i), CIHQ modified its standards to require the hospital update the patient's plan of care when restraints or seclusion are utilized.
- To meet the requirements at § 482.13(e)(5), CIHQ modified its standards to include the provision allowing other licensed independent practitioners, who are responsible for the care of the patient, to write orders for restraint or seclusion.
- To meet the requirements at § 482.13(e)(8)(ii), CIHQ modified its standards to include the reference to a physician or other licensed independent practitioner, as delineated at § 482.12(c).
- To meet the requirements at § 482.13(e)(11), CIHQ modified its standards to address that the physician and other licensed independent practitioners training requirements must be specified in hospital policy.
- To meet the requirements at § 482.13(g)(1), CIHQ modified its standards to permit the hospital to

communicate deaths to CMS by facsimile or electronically as determined by CMS.

- To meet the requirements at § 482.13(h)(1), CIHQ modified its standards to require the hospital to inform each patient of his or her visitation rights.
- To meet the requirements at § 482.22(a)(2), CIHQ modified its standards to require that a candidate who has been recommended by the medical staff and appointed by the governing body be subject to all medical staff bylaws, rules, and regulations, in addition to the requirements contained at § 482.22.
- To meet the requirements at § 482.23(b)(3), CIHQ modified its standards to include language that a registered nurse must supervise the care of each patient.
- To meet the requirements at § 482.23(c)(1), CIHQ modified its standards to address biologicals.
- To meet the requirements at § 482.23(c)(1)(ii), CIHQ modified its standards to address pre-printed and electronic standing orders, order sets, and protocols for orders related to the preparation and administration of drugs and biologicals.
- To meet the requirements at § 482.23(c)(4), CIHQ modified its standards to address the requirement that blood and intravenous medication administration occurs only in accordance with state law and approved medical staff policies and procedures.
- To meet the requirements at § 482.24(c)(1) through (c)(3)(iv), CIHQ modified its standards to address the requirements related to the appropriate authentication of all orders, including verbal orders; the appropriate use of standing orders, order sets and protocols within nationally recognized guidelines; the periodic review of such orders and protocols; and the authentication of such orders and protocols within the medical record.
- To meet the requirements at § 482.25, CIHQ modified its standards to address the medical staff's responsibility to oversee the development of policies and procedures to minimize drug errors.
- To meet the requirements at § 482.25(a), CIHQ modified its standards to require that the pharmacy or drug storage area be administered in accordance with accepted professional principles.
- To meet the requirements at § 482.25(b)(4), CIHQ modified its standards to limit the removal of drugs and biologicals from the pharmacy or storage area only by personnel designated in the policies of the medical

staff and pharmaceutical service, in accordance with federal and sState law.

- To meet the requirements at § 482.25(b)(5), CIHQ modified its standards to address the medical staff's responsibility to predetermine a reasonable time to automatically stop drugs and biologicals.
- To meet the requirements at § 482.25(b)(6), CIHQ modified its standards to address the immediate reporting of drug errors, adverse reactions, and incompatibilities to the attending physician.
- To meet the requirements at § 482.26, CIHQ modified its standards to clearly identify radiologic services as a service that the hospital is required to provide its patients.
- To meet the requirements at § 482.41(a), CIHQ modified its standards to delineate that building inspections and maintenance are to be conducted on an on-going basis. CIHQ also modified its standards to specify that if a hospital intends to provide medical treatment to the victims of a disaster, it must be in compliance with NFPA99, Section 11-3.
- To meet the requirements at § 482.41(b)(7) and NFPA 101 (LSC) 18/19.7.1, CIHQ modified its standards to require: a written evacuation and relocation plan be available to all supervisory personnel and employees; that employees are informed of their duties under the plan; and that a copy of the plan is to be readily available at all times in the telephone operator's position or at the security center. In addition, CIHQ modified its standards to require that the hospital instruct employees on life safety procedures and devices.
- To meet the requirements at § 482.41(b)(7), the NFPA 101 (LSC) 18/19.7.2.1, and the Life Safety Code Annex A 19.7.1.2, CIHQ modified its standards to require signal transmission of alarms for all fire drills and that all fire drills be scheduled unannounced on a random basis.
- To meet the requirements at § 482.43, CIHQ modified its standards to address the hospital's responsibility to have a discharge planning process in writing that applies to all patients.
- To meet the requirements at § 482.43(b)(6), CIHQ modified its standards to require that the results of the discharge planning evaluation be discussed with the patient or an individual acting on behalf of the patient.
- To meet the requirements at § 482.51, CIHQ modified its standards to specify that if outpatient surgical services are offered, the services must be

consistent in quality with inpatient surgical services.

- To meet the requirements at § 482.51(b)(5), CIHQ modified its standards to require that the operating room register be complete and up-to-date.
- To meet the requirements at § 482.51(b)(6), CIHQ modified its standards to address the requirement that an operative report must be written or dictated immediately following surgery and signed by the surgeon.
- To meet the requirements at § 482.56(a)(2), CIHQ modified its standards to include the reference to part 484 of the Code of Federal Regulations.
- To meet the survey process requirements in Appendix A of the SOM, CIHQ revised its policies outlining the survey size and composition to require that every survey will include at least one registered nurse with hospital survey experience.
- To meet the survey process requirements in Appendix Q of the SOM, CIHQ revised its policies to require notification to CMS of an immediate jeopardy situation, the content of the CMS notification, and the appropriate level of citation related to immediate jeopardy findings.
- To meet the requirements found at Section 2728B of the SOM, CIHQ revised its policies to require a more detailed monitoring plan that includes frequency of monitoring, duration of monitoring, sample size and target threshold, as part of a hospital's plan of correction for deficiencies found on survey.
- To meet the requirements found at Section 2005A2 of the SOM, CIHQ revised its policies to require the issuance of an accreditation denial for hospitals initially seeking participation in the Medicare program when the hospital has been found to be non-compliant with a condition of participation.

- To meet the requirements at § 498.13 and Section 2008D of the SOM, CIHQ revised its policies to clearly state that the final accreditation decision is based on the final survey report in which the provider meets all requirements or the date, which the provider is found to meet all conditions but has lower level deficiencies and CIHQ has received an acceptable plan of correction.

- To meet the requirements at Section 3012 of the SOM, CIHQ revised its policies to accurately reflect the requirement that follow-up surveys must be conducted within 45 calendar days from the survey end-date of the survey, which the condition level finding was cited.

- To clarify the survey process and to ensure the consistent application of survey activities, CIHQ updated its policies, survey tools and guidance to surveyors related to tracer activities, patient interviews, and staff interviews.

- To eliminate any real or perceived conflict of interest between CIHQ's consulting services through "Accreditation Resource Services" and its accreditation activities, CIHQ updated its plan to ensure that both entities are separated by a firewall and that information is not shared.

B. Term of Approval

Based on our review and observations described in section III of this final notice, we have determined that CIHQ's requirements for hospitals meet or exceed our requirements. Therefore, we approve CIHQ as a national accreditation organization for hospitals that request participation in the Medicare program, effective July 26, 2013, through July 26, 2017.

V. 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 (44 U.S.C. 35).

(Catalog of Federal Domestic Assistance Program No. 93.778, Medical Assistance Program; No. 93.773 Medicare—Hospital Insurance Program; and No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: July 2, 2013.

Marilyn Tavenner,

Administrator, Centers for Medicare & Medicaid Services.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-9080-N]

Medicare and Medicaid Programs; Quarterly Listing of Program Issuances—April Through June 2013

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

ACTION: Notice.

SUMMARY: This quarterly notice lists CMS manual instructions, substantive and interpretive regulations, and other **Federal Register** notices that were published from April through June 2013, relating to the Medicare and Medicaid programs and other programs administered by CMS.

FOR FURTHER INFORMATION CONTACT: It is possible that an interested party may need specific information and not be able to determine from the listed information whether the issuance or regulation would fulfill that need. Consequently, we are providing contact persons to answer general questions concerning each of the addenda published in this notice.