



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-3338-FN]

Medicare and Medicaid Programs: Approval of an Application from the Center for Improvement in Healthcare Quality for Continued CMS Approval of its 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) for continued recognition 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, 2017 through July 26, 2023.

FOR FURTHER INFORMATION CONTACT: Lillian Williams (410) 786-8638, Monda Shaver, (410) 786-3410, or Patricia Chmielewski, (410) 786-6899.

SUPPLEMENTARY INFORMATION:

I. Background

A healthcare provider may enter into an agreement with Medicare to participate in the program as a hospital provided certain requirements are met. Section 1861(e) of the Social Security Act (the Act) establishes criteria for providers seeking participation in Medicare as a hospital. 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 42 CFR part 488. The regulations at 42 CFR part 482

specify the specific conditions that a provider must meet to participate in the Medicare program as a hospital. Hospitals that wish to be paid under the Medicaid program must be approved to participate in Medicare, in accordance with 42 CFR §440.10(a)(3)(iii).

Generally, to enter into a Medicare hospital provider agreement, a facility must first be certified as complying with the conditions set forth in part 482 and recommended to the Centers for Medicare & Medicaid Services (CMS) for participation by a State survey agency. Thereafter, the hospital 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 must 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. The regulations at §488.5(e)(2)(i) require an accrediting organization to reapply for

continued approval of its Medicare accreditation program every 6 years or sooner as determined by CMS. The Center for Improvement in Healthcare Quality's (CIHQ's) term of approval as a recognized Medicare accreditation program for hospitals expires July 26, 2017.

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 24, 2017, we published a proposed notice in the **Federal Register** (82 FR 11579) announcing CIHQ's request for continued approval of its Medicare 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 §488.5, we conducted a review of CIHQ's Medicare hospital accreditation 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 hospital surveyors; (4) ability to investigate and respond appropriately to complaints against accredited hospitals; and, (5) survey review and decision-making process for accreditation.

- A comparison of CIHQ's Medicare accreditation program standards to our current Medicare hospital Conditions of Participation (CoPs).

- A documentation review of CIHQ's survey process to do 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 we require of State survey agencies, including periodic resurvey and the ability to investigate and respond appropriately to complaints against accredited hospitals.

- ++ Evaluate CIHQ's procedures for monitoring hospitals it has found to be out of compliance with CIHQ's program requirements. (This pertains only to monitoring procedures when CIHQ identifies non-compliance. If non-compliance is identified by a State survey agency through a validation survey, the State survey agency monitors corrections as specified at §488.9(c)).

- ++ Assess CIHQ's ability to report deficiencies to the surveyed hospitals and respond to the hospital'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 CIHQ's staff and other resources.

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

++ Confirm CIHQ's policies with respect to surveys being 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 24, 2017 proposed notice also solicited public comments regarding whether CIHQ's requirements met or exceeded the Medicare CoP for hospitals. There were no comments submitted.

IV. Provisions of the Final Notice

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

We compared CIHQ's hospital accreditation requirements and survey process with the Medicare CoPs at part 482, and the survey and certification process requirements of parts 488 and 489. CIHQ's standards crosswalk, which maps CIHQ's standards with the corresponding requirements under the Medicare CoPs, was also examined to ensure that the appropriate CMS regulation was included in citations as appropriate. We reviewed and evaluated CIHQ's hospital application, conducted as described earlier. As a result, CIHQ has revised its materials, standards, and certification processes to reflect the following Medicare requirements:

- §482.12: Updated the summary description of this provision in the crosswalk to be consistent with its accreditation standards.
- §482.12 (a)(1) through (10): Updated the summary description of this provision in the crosswalk to be consistent with its accreditation standards.
- §482.12(a)(10): Revised its standards to address the hospital's responsibility to

consult directly with the medical staff.

- §482.12(c): Updated the summary description of this provision in the crosswalk to be consistent with its accreditation standards.

- §482.12(c)(1)(ii): Updated the CFR citation to properly reference the regulatory requirement on its standards crosswalk.

- §482.12(c)(2): Updated the CFR citation to properly reference the regulatory requirement on its standards crosswalk.

- §482.12(c)(4)(i): Clarified the use of the word “develops” to indicate if the condition was present on admission or developed during the hospitalization on its standards crosswalk.

- §482.12(f)(2): Revised its standards to ensure the medical staff have written policies and procedures for appraisals of emergencies, initial treatment and referral.

- §482.13(a)(1) and §482.13(a)(2): Updated the summary description of these provisions in the crosswalk to be consistent with its accreditation standards.

- §482.13(a)(2)(i): Revised its standards to ensure the patient’s right to submit “written or verbal” grievances.

- §482.13(a)(2)(ii), §482.13(b)(3), §482.13(b)(4) and §482.13(c)(2): Updated the summary description of these provisions in the crosswalk to be consistent with its accreditation standards.

- §482.13(e)(5): Updated the CFR citation to properly reference the regulatory requirement.

- §482.13(e)(6) §482.13(f)(1)(ii), §482.13(g): §482.13(g)(2), §482.13(h),§482.21(b)(1), §482.21(d)(2), and §482.21(d)(4): Updated the summary description of these provisions in the

crosswalk to be consistent with its accreditation standards.

- §482.22 (a)(2): Updated its standards to reflect that temporary practice privileges are granted by the governing body.

- §482.22(b)(1): Updated the summary description of this provision in the crosswalk to be consistent with its accreditation standards.

- §482.22(b)(3): Revised its standards to reflect CMS requirements for medical staff organization and accountability.

- §482.22(b)(4): Updated the summary description of this provision in the crosswalk to be consistent with its accreditation standards.

- §482.23(c)(4): Updated its standards to fully address requirements for blood transfusions.

- §482.24(b): Updated its standards to fully address requirements for the form and retention of medical records.

- §482.24(c)(2) through (c)(4)(viii): Updated the Medicare regulatory language on its standards crosswalk to ensure that its accreditation standards are consistent with Medicare standards.

- §482.25(b)(2)(ii): Updated the crosswalk and standard to add references to the Comprehensive Drug Abuse Prevention and Control Act of 1970.

- §482.26: Updated the summary description of this provision in the crosswalk to be consistent with its accreditation standards.

- §482.41: Revised its standards to reflect the requirements of the “Physical Environment”.

- §482.43: Revised its standards to ensure that the hospital discharge planning process applies to all patients.
- §482.51(b)(6) and §482.56(a)(2): Updated the summary description of these provisions in the crosswalk to be consistent with its accreditation standards.
- §482.56(b)(2): Revised its standards to address the requirements at §409.17 related to physical therapy, occupational therapy, and speech language pathology services.
- §482.57(b)(3): Updated the CFR citation to properly reference the regulatory requirement on its crosswalk.
- §482.57(b)(4): Updated the CFR citation to properly reference the regulatory requirement on its crosswalk and in its accreditation standards.
- §488.4(a)(6): Revised its standards to include a process to track and trend complaints received.
- §488.5(a)(4)(ii): Revised its standards to ensure that an appropriate number of open, inpatient medical records are fully reviewed during the survey process.
- §488.5(a)(4)(iv): Revised its standards to assure that findings of non-compliance are documented under all appropriate CMS standards where non-compliance is found; and that adverse findings for each CoP are reviewed for manner and degree of non-compliance and subsequently cited at the appropriate level (that is, condition versus standard level).
- §488.5(a)(7) through (9): Revised its standards to ensure that newly hired surveyors receive orientation so as to ensure AO compliance with these provisions.
- §488.26(b): Revised its standards to improve surveyor documentation to include the appropriately detailed deficiency statements that clearly support the determination of

noncompliance and level of deficiency.

- §489.13: Revised its standards to reflect CMS policy regarding effective dates of participation in the Medicare program and develop a plan for monitoring for sustained compliance.
- CIHQ revised its complaint policy and procedure to clearly identify the individual(s) that are responsible for triaging complaints submitted to the accrediting organization.
- CIHQ revised its policy to clarify that an “Immediate Jeopardy” finding remains cited at the Conditional level, even if abated while onsite.

B. Term of Approval

Based on our review and observations described in section III of this final notice, we have determined that CIHQ’s hospital program requirements 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, 2017 through July 26, 2023.

V. 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.).

Dated: June 20, 2017

Seema Verma,

Administrator,

Centers for Medicare & Medicaid Services.

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