Getting Accreditation
A Look at Accreditation Requirements for DNV GL & CIHQ

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DNV GL Healthcare

Definitions:

- **Accredited Organization**: When a healthcare organization is currently accredited by DNV.
- **Applicant Organization/Applicant**: When a healthcare organization has applied for but not received DNV accreditation.
- **CAP**: Corrective Action Plan.
- **CMS**: Centers for Medicare and Medicaid Services.
- **CoPs**: Medicare Conditions of Participation for Hospitals.
- **Deemed Status**: Deemed compliant with CMS standards.
- **DNV**: DNV GL Healthcare Inc.
- **ISO 9001**: International Organization for Standardization Quality Management System.
- **NIAHO**: National Integrated Accreditation for Healthcare Organizations.
The NIAHO Accreditation Program

- NIAHO is an integrated accreditation program offered by DNV.
- This hospital accreditation program integrates the ISO 9001 Quality Management System requirements with the Medicare CoPs.
- DNV has been approved by CMS for deeming authority to determine healthcare organizations in compliance with COPS.
Medicare Deemed Status

A Medicare deemed status survey with DNV will consist of:

1. A survey for compliance with the NIAHO accreditation requirements; AND
2. Compliance with or Certification to the ISO 9001 Quality Management System within 3 years of initial NIAHO accreditation

- **Compliance** to ISO 9001 Requirements must be done through DNV
- **Certification** to ISO 9001 can be achieved through DNV or another Accredited Registrar
Accreditation & Certification Process

Step 1:

- The Applicant Organization submits a completed DNV Accreditation Application
  - If they choose DNV as the ISO Registrar this should include an ISO 9001 Certification Application

Step 2:

- DNV reviews the information and provides a fee structure based on the Applicant’s complexity and services requested.
Accreditation & Certification Process

Step 3:
- DNV puts together a survey team to conduct an on-site survey

Step 4:
- After the on-site accreditation survey the Applicant will be notified that the next survey will occur any time from the 9th - 12th month following the initial survey.
Surveys- Objective

- Analyze information about the organization
- Identify areas of potential concern to be investigated
- Determine if those areas or any special features of the organization require additional surveyors
Surveys-Location

The team will survey:

- All departments, services and locations that bill for services under the Applicant’s provider number and are considered part of the organization
- Any contracted patient care activities located on organization campuses or locations
Surveys-Team Size & Composition

Each team will include:

a. A Registered Nurse or Physician with hospital survey experience; and

b. A Physical Environment Specialist

Example: a mid size hospital of 200 beds would include 3 surveyors who would be at the facility for 2 or more days.
Surveys - Team Size & Composition

Team size and composition are normally based on:

1. Size of facility
2. Complexity of services offered
3. Type of survey to be conducted
4. Whether the facility has special care units or off site clinics or locations
5. Whether the facility has a historical pattern of serious deficiencies or complaints
Surveys- Conflict Check

DNV will verify with the team members before the survey that:

- There is no conflict of interest
- That no member of the team has assisted the Applicant Organization in preparation
- That no member of the team has served as a consultant
- That no member of the team has served as a former or current employee of the Applicant
Survey- Opening Meeting

The survey team leader will:

- Explain the purpose and scope of the survey
- Provide a schedule of survey activities
- Introduce survey members and their responsibilities
- Explain the various documents they may request
- Obtain name, locations and phone numbers for key staff to whom questions should be addressed
- Request documents requested for Document Review as listed no later than 3 hours after the request is made.
- Take a patient sample size
Surveys - What Surveyors are Looking For

Surveyors will pay attention to:

- Patient care
- Staff member activities
- Equipment
- Documentation
- Sounds
- Smells
- Storage, security & confidentiality of records
- Reporting practices
- What is missing and what should not be there
- Integration of services
Surveys- Patient Sample Size

- The number of clinical records selected for review will typically be based on the Applicant Organization’s average daily census.
- At least one patient from each inpatient unit will be selected.
- A sample of outpatients will be selected.
- Surveyors will try to select patients with open patient files first.
Surveys- Organization Documentation

In addition to the formal Document Review DNV will want to see:

- Patient’s clinical records
- Plans of care and discharge plans
- Open patient records rather than closed records
- Personnel files
- Policy & Procedure Manuals
- Contracts
- Organization Activity minutes
Surveys-Closing Meeting

• The Applicant organization determines which hospital staff will attend the closing meeting.

• The staff must wait until the surveyor finishes discussing a given deficiency before commenting.

• The organization will have an opportunity to present new information after the closing meeting for consideration after the survey.

• All findings will be discussed here.
Post Survey Activities

Report

- A preliminary report will be completed by the Survey team and issued.
- DNV will forward the final survey report to the organization within 10 days of the last date of the survey.

Determining Conformity

- There are 2 categories of nonconformity:
  1. Category 2 (Less serious)
  2. Category 1 (More serious)
Nonconformity- Category 2

Does not indicate a system breakdown or raise a doubt that services will meet requirements.

Examples:

• An isolated non-fulfillment of a requirement that is otherwise properly documented and implemented

• Inconsistent practice compared to other areas

• Significant enough to warrant the Applicant to take action to prevent future occurrence

• Has the potential for becoming a Category 1 nonconformity
Nonconformity- Category 1

Where objective evidence exists that a requirement has not been addressed, a practice differs from the defined system or the system is not effective.

Examples

- One or more required system elements is absent
- A situation raises significant doubt that the services will meet specified requirements
- A Category 2 nonconformity that is persistent/not corrected
- A situation that would have the capability to cause patient harm or does not meet a standard of care
Nonconformity- Category 1
Condition Level Finding

A Condition Level Finding is a Category 1 nonconformity where the Applicant is completely or substantially out of compliance with the requirement.

- Finding is made on a case-by-case basis in DNV’s sole discretion
- All Condition Level Findings will require a follow-up survey prior to the next annual survey.
Corrective Action Plans

A Corrective Action Plan (CAP) must be delivered to DNV within 10 calendar days from date of the written report. It must identify:

- The **root cause** of the nonconformity;
- The **actions taken** to correct the nonconformity;
- Other areas that have the **potential to be affected** by the same nonconformity;
- The **changes that will be made** to ensure that the nonconformity does not recur;
- The **timeframe for the implementation**;
- The **person responsible** for implementing the corrective action measure(s) and,
- The **performance measure(s) and/or other supporting evidence** that will be monitored to ensure the effectiveness of the corrective action(s) taken.
Within 60 days, the Applicant shall submit:

- performance measures
- data
- findings
- results of internal reviews
- other supporting documentation, including timelines to verify implementation of the corrective action measures.

If there is a Condition Level Finding, a follow-up survey prior to the next annual survey will also be required to determine compliance with the specific Category 1 Nonconformity.
CAP-Category 2

If the CAP requirements are met, validation of effective implementation of the agreed corrective action plan will take place at the next annual survey.

- Failure to comply with the requirements of the CAP regarding nonconformities may also result in a Condition Level Finding, which could result in Jeopardy Status for the Applicant.
Accreditation in Jeopardy

- Failing to submit a required CAP and/or related documentation
- Failure to meet reasonable timelines established in CAP
- Failure to maintain the ISO quality management system or be certified to ISO 9001 within 3 years the first NIAHO® deemed survey.
- Violating terms of the signed accreditation agreement, including non-payment of fees or refusal of access.
- Failure to respond adequately to nonconformities identified
- Making false public claims regarding accreditation
- Delivering patient care or services without valid license or certification
- Non-compliance with statutory and regulatory requirements of state or federal law
Follow Up/Special Survey

A Follow-Up Survey will be performed when:

- Compliance regarding a nonconformity has been issued, and cannot be determined to be corrected and implemented with contact to the Applicant or written documentation of objective evidence;

A Special Survey will be performed when:

- A patient or patient family complaint to DNV or media coverage of issues, cannot be resolved through evaluation of data findings, internal audits, or other documentation as requested by DNV

- CMS informs DNV of a concern based on information they may have received from another source

- When a situation within the definition of Immediate Jeopardy is identified.
  - Noncompliance that has caused, or is likely to cause, serious injury, harm, impairment, or death of a patient or is an immediate threat to life.
Appeals Procedure

Appeals received by DNV will be:

- Registered into a log to record the progress to completion
- Acknowledged without undue delay
- Reviewed and Answered

It shall be submitted in writing stating:

- Basis of appeal
- Relief being requested
Accreditation

Based on successful survey findings and/or CAP follow-up all of this will be presented to the Accreditation Committee for their decision regarding the accreditation status of the Applicant. If approved, the Applicant Organization will receive a 3 DNV Accreditation and, if appropriate, a 3 year Certification or Compliance for meeting the ISO 9001 Quality Management System requirements, subject to the approval of the Certification Body for ISO 9001.
Continued Compliance

Continuing NIAHO Accreditation:

• Requires a successful annual survey that validates continuing compliance with NIAHO requirements as well as continued ISO 9001 compliance or Certification following the ISO 9001 3 year grace period

Continuing ISO 9001 Compliance:

• Requires annual ISO Periodic Surveys and a full ISO compliance or Certification Survey done triennially. These will take place concurrently with the annual NIAHO Accreditation Survey
The Center for Improvement in Healthcare Quality

Definitions:

- CIHQ - The Center for Improvement in Healthcare Quality
- CCN - CMS Certification Number
CIHQ Accreditation Process

Step 1:
- Submit a formal application to CIHQ requesting accreditation

Step 2:
- Application must be completed and accepted

Step 3:
- Survey must be conducted

Step 4:
- Once accredited the hospital must notify CIHQ of substantive changes e.g. change of ownership, opening a new physical location, establishing a new clinical program or service or closure of a physical location or program.
Permission to Survey

CIHQ requires complete and unfettered access to an Applicant Organization’s:

- facility(s)
- documents
- medical records
- staff
- patients and
- other sources necessary to determine compliance to CIHQ standards and requirements.
Forbidden Uses of Surveyors

Organizations may not employ, retain, contract with or otherwise utilize CIHQ surveyors for:

a) Consulting services

b) To provide tools or documents to assist in accreditation compliance

c) To provide education programs on CIHQ standards

d) To review appeals or corrective action plans

e) To conduct mock surveys
Surveys- Conflicts of Interest

- Surveyors may not survey a hospital if the surveyor is:
  - Currently employed or has been employed by the Organization within the past 5 years
  - Is currently or has been in the past 5 years on the medical staff or granted privileges to practice in the organization
  - Has an ownership interest or receives money from the organization
  - Serves on the Board of the organization or in another professional capacity

Surveyors and staff persons are required to disclose this.
Surveys- Full Surveys

- This survey is conducted the first time an organization applies for accreditation.

**Triennial Survey** - This is a full survey conducted for existing accredited organizations no later than 36 months after the organization’s last full survey.
Surveys- Focused Surveys

Mid-Cycle Survey

- This is an abbreviated survey conducted between 16-20 months from the organization’s last full survey
  - 1-2 days in length
  - Focuses on the organization’s compliance to new or revised standards or requirements as well as standards and requirements that address high risk patient care processes.
  - The agenda and scope of the survey is developed annually
Surveys- Focused Surveys

Complaint Survey

- This is a survey performed in response to a complaint received about an accredited organization from a patient or surrogate decision maker.
  - 1 day
  - 1 surveyor
  - No set agenda
Surveys - Focused Surveys

Follow Up Survey

Conducted whenever:

- Organization sustains an immediate threat to health and safety deficiency
- Organization sustains a Condition Level Deficiency
  - Will be conducted within 45 calendar days from the survey end date of the survey in which the condition level deficiency was cited
  - 1 day
  - No set agenda
  - 1 surveyor
Surveys- Review Process

Preliminary Report

- Following the conclusion of the survey the team leader will produce a preliminary report, to assure:
  - There is sufficient information in a finding to appropriately assign a deficiency
  - The deficiency has been assigned to the appropriate CIHQ standard
  - The deficiency has been assigned an appropriate level of severity

Final Report

- Will be provided within 10 business days following completion of the survey
Right to Complain

- Organizations using CIHQ accreditation for deemed status must inform patients or their surrogate decision maker of the right to file complaints regarding quality of care concerns or safety issues to CIHQ.
- This information must be posted on the organization’s website and in registration areas at all of the organization’s sites of care.
Standard Level Deficiencies:

- When there is noncompliance with a standard or several standards that does not substantially limit a facility’s capacity to furnish adequate care or which would not jeopardize or adversely affect the health or safety of patients if the deficient practice recurred.

Course of action: CIHQ will inform the organization in writing and require the organization to investigate the complaint and provide a written response.

- CIHQ reserves the right to conduct an on-site survey within 10 business days following receipt of the complaint.
**Deficiencies - Condition Level**

**Condition Level Deficiencies:**

Noncompliance with a standard or several standards *that substantially limits a facility’s capacity to furnish adequate care or which would jeopardize or adversely affect the health or safety of patients if the deficient practice recurred*.

**Course of Action:** CIHQ will conduct an on-site survey within 1 week following receipt of the complaint.
Deficiencies- Immediate Threat to Health & Safety

Immediate Threat to Health & Safety:

Where the organization’s non-compliance with a one or more of CIHQ standards or requirements under the CMS CoPs *has caused or is likely to cause serious injury, harm, impairment or death to a patient.*

Course of Action: An onsite survey will be conducted within 2 business days of receiving the complaint

- Issuance of this deficiency will automatically change an organization’s accreditation status to “Accreditation at Risk” until the deficiency is corrected
Deficiencies- Immediate Threat to Health & Safety

CIHQ will notify CMS immediately if there is an actual or alleged deficiency that constitutes immediate threat to health and safety and requires further investigation including:

- Facility name & address
- CCN
- Date of survey
- Planned date for on-site survey
- Summary of issue(s)
- Date of last full accreditation survey
Rectifying Deficiency During Survey

- CIHQ allows organizations to correct identified deficiencies while the survey is occurring if:
  - It is minor, isolated & easily correctable
  - Correction does not require modifying existing policies, process or documents
  - Correcting does not require new or remedial education, training or competency validation of staff, physicians or other individuals

- Deficiencies rectified during the survey will still be cited and entered into the report and the organization will still be required to submit a corrective action plan.
Corrective Action Plans

- The Applicant is required to submit an acceptable CAP to CIHQ within 10 calendar days following receipt of the survey report and within 72 hours where there is an immediate threat to health & safety.

- Due dates for completion of CAPs should not exceed:
  - 60 days for standard deficiencies
  - 30 days for condition level deficiencies
  - From the date the CAP is received by the organization
  - CAP addressing an immediate threat to health & safety must be fully implemented at the time of submittal.

- A CAP must be developed and submitted for each deficiency identified and must identify
  a) Steps taken to correct deficiency
  b) How the CAP was implemented
  c) Monitoring process
  d) Title of person responsible for implementation
  e) Date CAP was implemented
Review of CAP

- If CAP is acceptable, Applicant will be notified in writing and no further action will be required.

- If CAP is unacceptable, Applicant will be notified in writing with specific modifications necessary and will be required to submit a second CAP within 7 calendar days.

- If 2nd CAP is unacceptable, Applicant will be notified in writing with specific modifications and a 3rd and final CAP will be required to be submitted within 5 calendar days.

- If the 3rd CAP is unacceptable, the Applicant’s status will be changed to “Accreditation at Risk”
Review of CAP

Immediate Threat To Health & Safety:

- Where a CAP is addressing these deficiencies and is acceptable no further action by the Applicant will be required, however a survey will be conducted by CIHQ to validate implementation of the CAP

- If the CAP is determined to be unacceptable, Applicant will be notified for the reasons in writing and it’s accreditation status will be changed to “Accreditation Denied/Withdrawn”

Accreditation at Risk

- Failure to implement CAP
- Failure to submit evidence CAP has been implemented
- Failure to request extension for implementation prior to due date
**Appeals**

First Level Appeals:

- If Applicant wants to appeal a finding it must notify CIHQ within 10 calendar days following receipt of survey report.

- If Applicant wants to appeal an accreditation decision it must notify CIHQ within 10 business days following issuance of decision.

- The appeal must address:
  - Basis for appeal
  - Why the Applicant believes decision was incorrectly rendered
  - Specific relief being requested
Second Level Appeals:

- If the Applicant does not accept the results of the first level it may request in writing to the Executive Director of CIHQ that its appeal be reviewed by the CIHQ Accreditation Board.
- No additional information may be submitted.
- The Applicant may request that they present their appeal in person. If granted it will be responsible for all costs related to the convening of the ARB.
- This decision will be final.
Accreditation

Surveys are pass/fail.

- If the organization is in compliance with CIHQ standards, requirements and policies at the time of survey or has successfully submitted an acceptable CAP within required time frames
- For initial accreditation, an organization will not be considered accredited until CAPs for all identified deficiencies have been accepted.
Publicly Shared Information

CIHQ will make the following information public to interested parties:

- Verification that the organization is accredited or seeking accreditation by CIHQ
- Current accreditation status
- Dates of the organization’s initial or last full triennial survey
- The expiration date of the organization’s current accreditation
Thank You

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