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ACCREDITATION PROCESS

 HOME INFUSION THERAPY



ACCREDITATION COMMISSION *for* HEALTH CARE



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I. Introduction

Accreditation Commission for Health Care (ACHC) is an independent, 501(c)(3) nonprofit accrediting organization that is certified to ISO 9001:2015 standards. ACHC is governed by a volunteer Board of Commissioners (Board) that is composed of healthcare professionals and consumers. The Accreditation Process contained in this document pertains to all organizations, whether they are applying for accreditation for the first time, renewing accreditation, adding or eliminating branches, or adding or eliminating services. As a result of changes in industry standards and/or regulatory changes, as well as ACHC's continuous internal review of its processes, ACHC may update its Accreditation Process. Accordingly, ACHC's services will be furnished in accordance with the most current version of the ACHC Accreditation Process in effect on the date of the survey or in effect at the time of any other activity.

II. Requirements

A. Organization Types

1. **Noncorporate:** Noncorporate organizations are defined as having 24 or less physical locations.
2. **Corporate:** Corporate organizations are defined as having 25 or more physical locations.

NOTE: The Accreditation Process is written for noncorporate and corporate organizations, unless otherwise specified. ACHC makes the final determination in defining a physical location.

B. Accreditation Types

Organizations may apply for the following type of accreditation:

1. Home Infusion Therapy Program

C. Eligibility Requirements

The organization may apply for accreditation if the following eligibility requirements are met.

Home Infusion Therapy Organizations must:

1. Be currently operating within the United States and/or its territories.
2. Be licensed according to applicable state and federal laws and regulations, and maintain all current legal authorization to operate.
3. Have completed the Medicare Enrollment Application Form CMS-855B.
4. Have established policies and procedures.
5. Demonstrate it is able to provide all services needed by patients served.
6. Have on staff a pharmacist, physician or registered nurse.
7. Be in compliance with all federal requirements, including Home Infusion Therapy Conditions for Coverage.
8. Have served a minimum of three patients. If a home infusion therapy supplier is in a rural area as defined by CMS, it should have served at least two patients.
9. Clearly define the services it provides directly or under contract.
10. Submit all required documents and fees to ACHC within specified time frames.

D. ACHC Home Infusion Therapy Service

Home Infusion Therapy Supplier (HITS) (Medicare Certified):

Home Infusion Therapy Supplier (HITS) services involve the administration of parenteral medications via various accesses and ports provided by a qualified Registered Nurse (RN), Licensed Practical Nurse (LPN), or skilled professional, as allowed by state regulations, specifically trained in these specialized services. These services are provided in the home. A Registered Nurse or Pharmacist is responsible for supervision of all HITS services.

NOTE: Beginning in 2021, providers seeking to meet the Conditions for Coverage (CfCs) to receive Medicare reimbursement for infusion nursing services provided in the home must be accredited under ACHC's Home Infusion Therapy Accreditation program

III. Principles Governing the Accreditation Survey

A. Compliance

During the accreditation survey, ACHC determines whether the organization is meeting the intent of ACHC Accreditation Standards. Proof of compliance is based upon items such as:

1. Review of patient records
2. Personnel files
3. Policies and procedures
4. Observations
5. Interviews

It is the organization's responsibility to ensure compliance with the ACHC Accreditation Standards at all times during the accreditation period. ACHC will release and communicate any updates/changes to ACHC Accreditation Standards every year on or around February 1. These updates/changes will have an effective date of June 1 of the same year in which they are released. However, in response to regulatory changes or requirements, ACHC Accreditation Standards may be updated at any time. Organizations must be compliant with any changes on the effective date.

B. Education

While the organization is preparing for its survey, the organization's Account Advisor is available to provide assistance with the accreditation process. Clinical Managers are available for interpretation of ACHC Accreditation Standards or suggestions on how to implement them. During the survey, ACHC Surveyors will provide education to help the organization achieve optimum performance.

C. Types of Surveys

1. **Initial Survey:** An Initial Survey* is conducted on organizations that apply for ACHC accreditation for the first time. Initial Surveys are unannounced.
2. **Renewal Survey:** A Renewal Survey* is conducted on organizations that are currently accredited by ACHC. Renewal Surveys are conducted in the same format as an Initial Survey but during the Renewal Survey, the Surveyor also reviews previous deficiencies for compliance. Renewal Surveys are unannounced.
3. **Off-site Audit:** An off-site audit is conducted on a percentage of an organization's renewing locations based on a methodology which takes into consideration: history of complaints with client/patient-related deficiencies, risk potential as identified by

performance improvement data, infusion volume and previous survey results.

4. **Dependent Survey:** A Dependent Survey is a resurvey conducted on an organization that initially was not in compliance with ACHC Accreditation Standards. Dependent Surveys are unannounced.
5. **Corporate Survey:** A Corporate Survey is conducted on corporate organizations. Corporate Surveys provide the organization the opportunity to present policies and procedures and other relevant information that demonstrate compliance with the ACHC Accreditation Standards. Corporate Surveys are announced.
6. **Initial Sampling Survey:** An Initial Sampling Survey is conducted for corporate organizations seeking ACHC accreditation for the first time. This survey takes place following the Corporate Survey to validate the information presented. Initial Sampling Surveys are unannounced.
7. **Focus Survey:** A Focus Survey is conducted on organizations to ensure ongoing and continued compliance with ACHC Accreditation Standards. Focus Surveys can take place anytime throughout the accreditation period or for any organizational changes. Focus Surveys are unannounced.
8. **Complaint Survey:** A Complaint Survey is conducted on organizations that have a complaint filed against them. Should ACHC determine during its initial investigation that a site visit is required, ACHC will conduct a Complaint Survey to determine if the complaint is substantiated. Complaint Surveys are unannounced.
9. **Disciplinary Action Survey:** A Disciplinary Action Survey is conducted on organizations due to noncompliance from a previous survey, noncompliance of the ACHC Accreditation Standards and/or Accreditation Process, and/or a breach in the ACHC Accreditation Agreement. Disciplinary Action Surveys are unannounced.
10. **Virtual Survey:** A Virtual Survey is conducted using a virtual hosting solution that allows an audio, video, and camera web-based platform for virtual meetings, including, but not limited to: GoToMeeting, Microsoft Teams, Skype, Webex, and Zoom. Virtual surveys are offered to certain organization types, depending on the parameters set by ACHC, state licensure requirements, and regulations of the Centers for Medicare & Medicaid Services (CMS). Virtual surveys review the same material as an on-site survey, and the organization needs to show compliance with all ACHC standards, and state and federal requirements. Virtual surveys can be announced or unannounced, depending on the program.

* This is a comprehensive extended survey examining all of the ACHC Accreditation Standards and the CMS Conditions for Coverage (CfC).

IV. Accreditation Process Before the Survey

A. Register for Access to ACHC through Customer Central

1. Access Customer Central through the ACHC website at cc.achc.org.
2. Create username and password.
3. Receive Account Advisor's contact information.

B. Download ACHC Accreditation Standards

1. Available for organizations that have not previously obtained them.

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2. Once purchased, organization has unlimited access to all ACHC Accreditation Standards.
 3. Credit is applied for organizations that submit a deposit for accreditation.
- C. Complete ACHC Accreditation Application and Submit Deposit**
1. Complete online Accreditation Application in its entirety. (Paper format is available.)
 2. Complete statistical information for all physical locations. Based on governance, complexity of corporate structure, tax reporting and other factors, ACHC will determine the number of applications and number of surveys required.
 3. Submit nonrefundable deposit. (Applied toward accreditation fee.)
- D. Execute Agreement for Accreditation Services**
1. The following agreements outline the obligations of both ACHC and the organization. ACHC issues one of the following:
 - Agreement for Accreditation Services/Business Associate Agreement (BAA)
 - Agreement for Corporate Accreditation Services/ Business Associate Agreement (BAA)
 2. Sign and return the Agreement and BAA to ACHC within the specified time frames listed on the cover page.
 3. Failure to meet any terms of the Agreement or BAA may result in rescheduling or cancellation of the survey with fees assessed.
- E. Submission and Review of Preliminary Evidence Report (PER)**
1. Complete attestation on PER checklist (for initial applications only) to confirm existence of required policies and procedures.
 2. Upload the required PER checklist (for initial applications only) and documents through Customer Central. (Contact Account Advisor if organization is unable to submit electronically.)
 3. ACHC evaluates the content of all required documents and the ACHC Surveyor will discuss any questions with the organization during the survey.
 4. A review of all policies and procedures related to the ACHC Accreditation Standards is available to organizations for a fee.
- F. Scheduling**
1. Upon receipt of the required documents, the scheduling process is initiated.
 2. Organizations are allowed to choose up to 10 blackout days on which ACHC will not schedule a survey. Only two of these days can be Wednesdays. (NOTE: that choosing fewer blackout dates provides greater flexibility in scheduling the survey.)
 3. The following days do not need to be included in the organization's blackout days:
 - a. New Year's Day
 - b. Good Friday
 - c. Memorial Day
 - d. Independence Day
 - e. Labor Day
 - f. Thanksgiving Day and the following day

- g. Christmas Eve
 - h. Christmas Day
5. ACHC reserves the right to send a Surveyor preceptee as part of the survey team. A preceptee is sent at no charge to the organization. All ACHC Surveyors/preceptees must disclose any potential conflict of interest with the organization to ACHC before they are assigned to conduct the survey. Surveyors/preceptees with a confirmed conflict are not utilized for the survey being scheduled.

G. Postponement of Survey

1. **Organizations seeking a Medicare number:** Survey postponements must be requested in writing to the organization's Account Advisor. A call with a member of the clinical education team may be required.
 - a. For an unannounced survey, organizations may request a survey postponement after their pre-survey call. If no pre-survey call is performed, organizations may request a survey postponement after their application is sent to scheduling by their Account Advisor. On the day of the survey, organizations must follow the refusal process.
 - b. For an announced survey, organizations may request a survey postponement after their pre-survey call. If no pre-survey call is performed, organizations may request a survey postponement after their application is sent to scheduling by their Account Advisor. Starting the day before the survey, organizations must follow the refusal process.
 - c. If a postponement request is accepted, ACHC will invoice a postponement fee as listed in the Agreement for Accreditation Services. The postponement fee is required to be paid prior to rescheduling the survey. The organization is responsible for notifying the Account Advisor in writing of its readiness for survey. When notified, the Account Advisor will proceed with rescheduling the survey following the ACHC scheduling process. If the organization does not notify the Account Advisor within 180 days of the postponement date, the organization's deposit and application may be forfeited and the organization must re-apply for accreditation.
2. **Organizations with an active Medicare number:** Medicare regulations require agencies with an active Medicare number to be prepared for survey at all times. Organizations are not permitted to postpone their ACHC survey at any point after their pre-survey call. If no pre-survey call is performed, organizations are not permitted to postpone their ACHC survey at any point after their application is sent to scheduling by their Account Advisor. If an organization wishes to stop the survey process, they should contact their Account Advisor and request a call with a member of the clinical education team.

V. Survey Process

A. Noncorporate Organizations

1. **Opening Conference:** The opening conference may consist of the following, based on the organizational structure:
 - a. Introduction of the Surveyor(s).
 - b. Review of the tentative schedule.

- c. Review of questions on any documents from the application process.
- d. Q&A from the organization about the survey.
- 2. Tour of the organization**
- 3. Data Collection**
 - a. In order for ACHC to ensure that the organization is compliant with all ACHC Accreditation Standards, the survey focuses on the following:
 - Personnel file review.
 - Patient record review.
 - Financial/billing records.
 - Service contracts.
 - Risk management.
 - Performance Improvement (PI) activities.
 - Policies and procedures.
 - Observations.
 - Personnel and patient interviews.
 - Home visit:
 - i. When the surveyor arrives on site, the surveyor requests a schedule to review scheduled visits. The surveyor determines when the home visit will occur and conducts visit.
 - ii. If there are no scheduled visits, or the scheduled visits are a significant distance away:
 - The surveyor asks if the organization can arrange a visit
 - If the organization also has an ambulatory infusion center (AIC), the surveyor would watch a setup in the AIC.
 - The surveyor could watch a mock setup.
 - iii. The surveyor may call a patient to obtain any additional information if needed.
 - b. The organization authorizes ACHC to access the records listed above that are necessary to ascertain the degree of compliance with ACHC Accreditation Standards. ACHC complies with all HIPAA, privacy and security regulations.
 - c. The Surveyor's role is to review information presented and to clarify, observe and verify data that supports compliance with applicable ACHC Accreditation Standards.
- 4. Closing Conference**

The ACHC Surveyor conducts a closing conference with the organization's representatives.

 - a. This allows a final opportunity to clarify information or present data that may not have been reviewed by the Surveyor during the survey.
 - b. The ACHC Surveyor will provide a summary of organizational strengths and deficiencies.
 - c. The ACHC Surveyor does not issue an accreditation decision at the completion of the survey.

B. Corporate Organizations

1. **Corporate Survey:** Corporate organizations that do not provide patient services out of the corporate office will have an announced Corporate Survey that may include the following:
 - a. Opening conference led by ACHC:
 - Introduction of the survey team.
 - Introduction of the organization's personnel.
 - Review of the day's schedule.
 - b. Tour of the organization, if applicable.
 - c. Q&A from the organization about the survey.
 - d. Presentation of the organization's policies and procedures, as required by the ACHC Accreditation Standards.
 - e. Review of questions on any documents from the application process.
 - f. Review of corporate officer/senior management personnel files maintained at corporate office.
 - g. Presentation of the organization's Performance Improvement (PI) Plan and results of the ongoing monitoring.
 - h. Interviews with corporate management personnel.
 - i. Closing conference.
2. Following the Corporate Survey for new corporate organizations:
 - a. The ACHC survey team will conduct Initial Sampling Surveys at a specified number of locations to verify compliance with ACHC Accreditation Standards.
 - b. Once the Initial Sampling Surveys are completed, the data collected will be sent back to the organization's Account Advisor for processing.
 - c. Initial Sampling Surveys are conducted in the same format as the noncorporate survey process.
 - d. Following the Corporate Survey, ACHC will begin conducting unannounced surveys at all of the remaining locations. These surveys will verify that the information presented during the Corporate Survey is being followed and meets ACHC Accreditation Standards.
 - e. These surveys will be conducted in the same format as the noncorporate survey process.
3. Following the Corporate Survey for renewal corporate organizations:
 - a. The ACHC survey team will conduct Initial Sampling Surveys at a specified number of locations to verify compliance with ACHC Accreditation Standards.
 - b. Once the Initial Sampling Surveys are completed, the data collected will be sent back to the organization's Account Advisor for processing.
 - c. Initial Sampling Surveys are conducted in the same format as the noncorporate survey process.
 - d. Following the Corporate Survey, ACHC will begin conducting unannounced surveys at a percentage of the remaining locations. These surveys will verify that the information presented during the Corporate Survey is being followed and meets ACHC Accreditation Standards.

- e. Surveys are conducted in the same format as the noncorporate survey process.
- f. Corporate sites that do not have an on-site survey will have an off-site audit.

C. Refusal of Survey

1. Organizations have the right to refuse an ACHC survey.
 - a. Announced surveys can be refused starting the day before the survey. Unannounced surveys can be refused the day of the survey. If an organization wishes to request a survey refusal, it must contact its Account Advisor and complete a Survey Refusal Form. A call with a member of the clinical education team may be required.
 - b. If an ACHC Surveyor arrives on site and the organization wishes to refuse, does not meet the eligibility criteria for an accreditation survey, or is not in operation during its posted business hours, the Surveyor will notify the Account Advisor of refusal. A call with a member of the clinical education team may be required. If possible, a Survey Refusal Form will be completed on site.
 - c. If an ACHC survey is refused, ACHC will invoice a refusal fee as listed in the Agreement for Accreditation Services. The refusal fee is required to be paid prior to rescheduling the survey. The organization is responsible for notifying the Account Advisor in writing of its readiness for survey. When notified, the Account Advisor will proceed with rescheduling the survey following the ACHC scheduling process. If the organization does not notify the Account Advisor within 180 days of the refusal date, the organization's deposit and application may be forfeited and the organization must re-apply for accreditation.

VI. Accreditation Process Post-Survey

A. Reviewing the Data Collected

1. **Scoring:** Following the conclusion of the accreditation survey, the ACHC Surveyor will submit all of the data collected to the organization's Account Advisor for processing. The information will be entered into an electronic tool that provides objective data for determining the accreditation decision.
2. **Preparing the Summary of Findings (SOF):** The Summary of Findings is prepared and describes all ACHC Accreditation Standards that were marked as a deficiency during the accreditation survey. Each ACHC Accreditation Standard marked as a deficiency contains a "Corrective Action" statement. This statement assists the organization in preparing a Plan of Correction (POC) to meet the ACHC Accreditation Standards.
3. **Accreditation Review:** All Summary of Findings are analyzed by the appropriate Clinical Manager or designee and evaluated by the Accreditation Review Committee to ensure consistency before a final accreditation decision is rendered.

B. Accreditation Decisions

1. **Approval of Accreditation:**
 - a. Accreditation is granted to organizations that are compliant with all ACHC Accreditation Standards and the Medicare Conditions for Coverage (CfC) at the time of the survey.
 - b. The accreditation effective date for new and renewal organizations that receive an Approval of Accreditation is determined as follows:

- **New Organization:** The accreditation effective date is the last day of the survey.
 - **Renewal Organization:** The accreditation effective date continues for an additional 36 months from the previous accreditation expiration date if the Renewal Survey is conducted before the expiration date. If the organization's survey takes place after the expiration date, the approval date starts on the last date of the survey.
2. **Accreditation Pending:**
- a. Accreditation Pending is based on the following criteria:
 - Results of the data collected during survey.
 - Noncompliance with any Medicare CfCs.
 - Number and/or severity of any deficiencies.
 - Decisions of the Clinical Manager/designee and Accreditation Review Committee.
 - b. Accreditation cannot be granted until a Plan of Correction (POC) is submitted and approved. Due dates are as follows:
 - POC is due to ACHC within 10 calendar days from the date of the organization's Accreditation Pending letter.
 - If adjustments to the POC are necessary, the organization must submit modifications to achieve an approved POC within 10 calendar days, as specified on the notification to the organization.
 - Organizations must have submitted an approved POC for achieving compliance no longer than 60 calendar days after the survey.
 - Failure to submit an approved POC within the required time frame will result in a change of accreditation status from Accreditation Pending to Denial of Accreditation.
 - If requested, evidence to support the implementation of the organization's POC is due to ACHC within 60 days following the date of the organization's Accreditation Pending letter.
 - Failure to submit requested evidence will result in termination of accreditation.
 - c. All Plans of Correction are reviewed by the Clinical Manager/designee. After reviewing the POC, ACHC may issue:
 - Approval of Accreditation.
 - A rejection of POC and require additional information.
 - Dependent Status (Section VI, B, 3).
 - d. If accreditation is granted following review of the Plan of Correction, the effective dates for new and renewal organizations are determined as follows:
 - **New Organization:** The effective date is the day the approved POC is received by ACHC. An approved POC is one that has been accepted by the Clinical Manager/designee.

- **Renewal Organization:** The accreditation effective date will continue for an additional 36 months from the previous accreditation expiration date if the Renewal Survey is conducted before the expiration date. If the organization's survey takes place after the expiration date, the approval date starts on the date the approved POC is received.

3. Dependent Status:

- Dependent Status is determined based on the following criteria:
 - Results of the data collected during survey.
 - Noncompliance with any Medicare CfCs.
 - Number and/or severity of any deficiencies.
 - Decisions of the Clinical Manager/designee and Accreditation Review Committee.
- The Plan of Correction (POC) is due to ACHC within 10 calendar days from the date of the dependent letter. ACHC will conduct a follow-up survey within 45 calendar days from the date of the notification letter, informing the agency of the dependent survey decision.
- The Surveyor submits the findings from the Dependent Survey to the organization's Account Advisor and a decision is made by the Clinical Manager/designee. Upon review, ACHC may issue:
 - Approval of Accreditation
 - Accreditation Pending
 - Denial of Accreditation (Section VI, B, 4)
- If accreditation is granted following a Dependent Survey, the effective accreditation dates for new and renewal organizations are determined as follows:
 - **New Organization with PTAN:** The effective date of accreditation is the last day of the Dependent Survey, if no deficiencies are identified. If deficiencies are identified during the Dependent Survey, the effective date of accreditation is the day the approved POC is received by ACHC from the Dependent Survey. An approved POC is one that has been accepted by the Clinical Manager/designee.
 - **Renewal Organization:** The accreditation effective date continues for an additional 36 months from the previous accreditation expiration date if the Dependent Survey is conducted before the expiration date. If the organization's survey takes place after the expiration date, the approval date starts the date the approved POC is received.

4. Denial of Accreditation:

- Denial of Accreditation is based on the following criteria:
 - Results of the data collected during survey.
 - Noncompliance with any Medicare CfCs.
 - Number and/or severity of any deficiencies.
 - Decisions of the Clinical Manager/designee and Accreditation Review Committee.

- b. If accreditation is denied, the organization can appeal the decision by following the steps outlined in the Appeals Process (Section VI, F).
- c. If accreditation is denied, the organization can reapply for accreditation when it is ready for survey.
 - At the time of reapplication, a new application must be submitted with a nonrefundable deposit.
 - ACHC will determine if a new PER is required.

C. Accreditation Documentation

1. Once an accreditation decision is made by the Clinical Manager/designee and the Accreditation Review Committee, the accreditation decision is given to the Account Advisor. The Account Advisor then prepares the proper documentation to send to the organization.
2. Based on the accreditation decision, the Account Advisor sends the following:
 - a. **Approval of Accreditation:** Accreditation Approval letter, Certificate of Accreditation, Summary of Findings and window decal.
 - b. **Accreditation Pending:** Accreditation Pending letter, Summary of Findings and Plan of Correction template.
 - c. **Dependent Status:** Dependent Status letter, Summary of Findings and Plan of Correction template.
 - d. **Denial of Accreditation:** Denial letter and Summary of Findings.
3. The Plan of Correction must be completed in its entirety, returned to ACHC and approved by the Clinical Manager/designee in order to be acceptable. The POC must be completed on the ACHC Plan of Correction template and must contain the following elements:
 - a. The standard that was out of compliance.
 - b. Corrective action to be taken.
 - c. Implementation date.
 - d. Title of individual responsible.
 - e. Process for continued compliance.
4. Once an organization is in full compliance with all ACHC Accreditation Standards and Medicare CfCs, ACHC will begin reporting the organization's accreditation to CMS Central Office.
5. If an organization is seeking accreditation and is issued a Denial decision, ACHC will report the organization's accreditation to CMS Central Office. The organization must be in compliance with all ACHC Accreditation Standards and Medicare CfCs before ACHC can report the organization's accreditation.
6. Once an organization receives an approval decision, the organization's accreditation information will be placed on the ACHC website for verification.

D. Dispute Process

Organizations, whether applying for the first time or renewing their accreditation, may formally request to dispute a standard(s) deficiency documented on the Summary of

Findings. If a company wants to dispute a Denial decision, it must follow the appeals process (refer to Section VI.F).

The procedure to dispute a standard(s) deficiency is as follows:

1. The organization submits a written request for dispute to its ACHC Account Advisor no later than 10 calendar days from the receipt of the Summary of Findings. Dispute requests will not be granted if:
 - a. The request is received after the 10-calendar day time frame.
 - b. An organization has an outstanding balance.
 - c. An organization has a payment plan that is not current.
2. The written request outlines the standard(s) noted in the Summary of Findings that the organization considers incorrectly determined by ACHC as a deficiency. The organization must provide evidence to support its contention that the organization was in compliance with the standard(s) at the time of the survey. Any evidence the organization submits must have been presented to and reviewed by the Surveyor(s) at the time of the survey. Evidence provided with the request letter will not be returned to the organization.
3. Upon receipt of a dispute request, ACHC sends an acknowledgement letter to the organization.
4. If the organization is required to submit a POC as a result of its survey, the organization must indicate on the POC any standard(s) deficiency being disputed.
5. The ACHC Review Committee will evaluate and determine if ACHC followed its stated Accreditation Process in conducting the organization's accreditation survey.
6. Any ACHC Review Committee member who has a conflict of interest with the organization under review will refrain from voting on the dispute.
7. Upon completion of the review, the ACHC Account Advisor notifies the organization of the ACHC Review Committee's decision to either uphold or reverse the original standard(s) deficiency noted on the Summary of Findings.
8. All decisions made by the ACHC Review Committee are final.

E. Appeal Process

Organizations, whether applying for the first time or renewing their accreditation, may formally request to appeal a Denial decision. The procedure to appeal a Denial of Accreditation is as follows:

1. The organization submits a written request for appeal to its ACHC Account Advisor no later than 30 calendar days from the date on ACHC's Denial letter. Appeals will not be granted if:
 - a. The request is received after the 30-calendar day time frame.
 - b. An organization has an outstanding balance.
 - c. An organization has a payment plan that is not current.
2. The written request outlines the standard(s) noted in the Summary of Findings that the organization considers incorrectly determined by ACHC as a deficiency. The organization must provide evidence to support its contention that the organization was in compliance with the standard(s) at the time of the survey. Any evidence the organization submits must have been presented to and reviewed by the Surveyor(s) at

the time of the survey. Evidence provided with the request letter will not be returned to the organization.

3. Upon receipt of the request for an appeal, ACHC will send an acknowledgement letter to the organization.
4. The ACHC Appeals Committee, composed of a minimum of three individuals who have clinical and/or program expertise, will evaluate and determine whether ACHC followed its stated Accreditation Process in conducting the organization's accreditation survey.
5. Any ACHC Appeals Committee member who has a conflict of interest with the organization under review will refrain from voting on the appeal.
6. Upon completion of the review, the ACHC Account Advisor will notify the organization in writing of the ACHC Appeals Committee's decision to either uphold or reverse the original Denial decision.
7. All decisions made by the ACHC Appeals Committee are final.

F. Continued Compliance

1. Accreditation is contingent upon continued compliance with the ACHC Accreditation Standards and the Accreditation Process. After an organization is granted accreditation, ACHC reserves the right to make unannounced Focus Survey visits any time during the accreditation period to ensure continued compliance with ACHC Accreditation Standards.
2. If a Focus Survey reveals noncompliance with any ACHC Accreditation Standards, a POC and supporting documentation are required. Based on the number and/or severity of deficiencies, the organization may be invoiced for the Focus Survey.

G. Renewing Accreditation

1. Accreditation is not automatically renewable. Approximately 12 months before the organization's expiration of accreditation, ACHC will notify the organization about the renewal process.
2. If the organization's renewal application and deposit are not submitted by the required due date listed on the renewal letter, sufficient time may not exist to schedule and complete a survey before the accreditation expiration date.
3. If the organization's accreditation expires, the organization's accreditation will not be reported to CMS Central Office and will affect the organization's ability to receive reimbursement from CMS for services provided.
4. If an organization's accreditation expires, the organization's accreditation information will be removed from the accredited organization list on the ACHC website.

H. Changing Accrediting Organizations

1. If an ACHC accredited Home Infusion Therapy supplier decides to change accrediting organizations, it needs to provide written notice to CMS at least 60 calendar days before its accreditation expiration date, stating that it has submitted an application for home infusion therapy accreditation under another CMS-approved home infusion therapy accreditation program. Failure to comply with this 60-calendar day requirement before the expiration of their current home infusion therapy accreditation status could result in a suspension of payment for services provided.

VII. Disciplinary Actions

Disciplinary actions can come from a nonconformance resulting from an ACHC survey and/or failure to remain in compliance with ACHC Accreditation Standards or Accreditation Process, and/or a breach in the ACHC Accreditation Agreement.

A. Noncompliance process

1. If the organization is placed Under Review:
 - a. ACHC notifies the organization.
 - b. ACHC determines which of the following actions will be taken:
 - ACHC may request written documentation.
 - ACHC may conduct a Disciplinary Action Survey.
 - If ACHC determines that Immediate Jeopardy might be present, the process as described in Section X.C will be followed.
 - ACHC may require a Plan of Correction be completed.
 - ACHC may require a payment.
 - c. Upon review of any documentation or Plan of Correction, ACHC may accept it, reject it or require additional information.
 - d. ACHC will render a decision:
 - Continuance of Accreditation
 - Accreditation remains Under Review
 - Termination
2. Accreditation may be terminated based on the number or severity of nonconformance or if it is thought that compliance with ACHC standards is not possible within a reasonable time frame.

B. Termination

Organizations accredited by ACHC must remain in compliance with ACHC Accreditation Standards; adhere to local, state and federal legal requirements; ensure the safety of their patients and staff; and meet commonly held standards of professional ethics and conduct.

Accreditation can be terminated any time during the accreditation cycle. A decision to terminate accreditation does not need to be preceded by a survey because problems with an organization's services can become apparent from a number of other sources. Therefore, if ACHC receives evidence of noncompliance with ACHC Accreditation Standards or other pertinent criteria, ACHC may decide to terminate accreditation if, in its judgment, it finds that one or more of the following conditions are present:

1. An immediate threat exists to patient safety, public health or staff safety. Such an immediate threat can arise from one incident on a single occasion that affects a single patient, a single staff member or a single member of the public.
2. ACHC determines, in its discretion, that the scope or severity of the organization's noncompliance with ACHC Accreditation Standards is so significant that it is infeasible for the organization to complete corrective action within 10 calendar days or within a reasonable time frame, as ACHC determines in its discretion under the circumstances.

3. The organization fails to comply or fails to maintain compliance with CMS Conditions of Participation, Conditions for Coverage (CfC), CMS Supplier Standards or CMS Quality Standards.
4. The organization falsifies documents or misrepresents information in seeking to achieve or retain accreditation, or in seeking or retaining some other license, certification, or authorization to operate, or to receive payment for services.
5. The organization, or a staff member, engages in any criminal conduct involving a felony, or engages in immoral, unethical, dishonest, incompetent or other unprofessional behavior that significantly adversely affects, or has the potential to significantly adversely affect, the safety or welfare of any patient or client, or the safe and effective delivery of the organization's services.
6. The organization does not fulfill contractual obligations during the accreditation cycle by failing to comply with post-accreditation obligations, as specified in the Agreement for Accreditation Services.

VIII. Notification of Changes

A. Notification Process

ACHC requires organizations to provide the required documentation described below within 30 days of a change occurring. Changes include: service addition or deletion; and change in the name, location, ownership or control of the organization. Failure to submit the required documentation within the 30-day time frame may result in a gap in accreditation.

B. Name Change

1. If an organization goes through a name change, the organization must notify ACHC of the change within 30 days of the change. The organization must complete and submit the "Name Change" form, which can be downloaded from Customer Central on the ACHC website. (The form is located under the "Forms" header. To download, select "Change of Name Request Form – Home Infusion Therapy." This form also can be completed electronically using an e-signature.)
2. ACHC may request additional documentation upon review. If approved, ACHC will issue a new accreditation certificate. If ACHC approves the name change, an organization must complete the following:
 - a. Submit form 855B with the organization's new name to CMS.
 - b. Upon receipt of an "Information Change Approval" letter from CMS, submit a copy to ACHC.
3. If it is determined a survey is necessary, the normal unannounced survey scheduling process will apply and the organization will be charged a survey fee.
4. If the organization is found to have substantial deficiencies during the survey, the accreditation for that location and/or the organization as a whole will be reviewed by the Clinical Manager/designee and the Accreditation Review Committee. Following the review, the organization may be placed Under Review.

C. Location Change

1. If an organization goes through a location change, the organization must notify ACHC of the change within 30 days. The organization should complete and submit the "Change of Location" form, which can be downloaded from Customer Central on the ACHC

website. (The form is located under the “Forms” header. To download, select “Change of Location Request Form – Home Infusion Therapy.” This form also can be completed electronically using an e-signature.)

2. ACHC may request additional documentation upon review. If approved, ACHC will issue a new accreditation certificate.
3. After ACHC approves the location change, complete the following:
 - a. Submit form 855B with the location change to CMS.
 - b. Upon receipt of the “Information Change Approval letter” from CMS, submit a copy to ACHC.
4. If it is determined a survey is necessary, the normal unannounced survey scheduling process will apply and the organization will be charged a survey fee.
5. If the organization is found to have substantial deficiencies during the survey, the accreditation for that location and/or the organization as a whole will be reviewed by the Clinical Manager/designee and the Accreditation Review Committee. Following the review, the organization may be placed Under Review.

D. Cessation or Interruption Within the Organization

1. If the organization has a cessation or interruption of all the organization’s operations, offerings of service and/or a deletion of any service that has received accreditation, the organization must notify ACHC via a notification letter. The organization’s notification letter to ACHC must include the following:
 - a. Effective date of the cessation or interruption.
 - b. Detailed description of the reason for the cessation or interruption.
2. Upon receipt of the written notification, ACHC will review and send an acknowledgment to the organization. The notification letter will be placed in the organization’s file. ACHC may request additional documentation before an acknowledgement letter is sent.
3. The organization will notify ACHC of any change in the status from the acknowledgment of the cessation or interruption of operations. Upon notification, ACHC will review the organization’s accreditation status and determine if a survey is required to ensure compliance with the ACHC Accreditation Standards and Medicare CFCs.

E. Branch Office Addition

1. ACHC defines a branch as a location serving patients, maintaining patient records and/or personnel files, and accepting referrals. Additions for a branch must fall under a parent location. The organization must complete and submit a Home Infusion Therapy Branch Addition Packet. The packets are located on Customer Central under the “Forms” header. To download, select: “Additional Site Location - Pharmacy.” The packet must be completed in full, including all sections and any additional information listed on the form.
2. A review of the documentation is performed and any missing information is requested from the organization in writing. Additional information may be requested prior to approving the branch addition. ACHC holds the branch addition documentation without further processing until the missing information is received from the organization.

Once all required documentation has been submitted, the Regulatory Department reviews the submitted documentation. A survey is based on several factors that include the original survey findings, where the organization is in the three-year accreditation cycle and how many locations have been added from the start of its accreditation.

3. Upon approval of the submitted documentation, ACHC issues accreditation based on the date that all required documentation was submitted. ACHC will not backdate an accreditation for any organization that sends notification after the branch opening. All fees must be paid in full before ACHC issues any accreditation documentation.
4. If it is determined a survey is necessary, the normal unannounced survey scheduling process will apply and the organization will be charged a survey fee. If it is determined a survey is not necessary, the organization will be charged a fee as indicated in the Accreditation Agreement.
5. If the organization is found to have substantial deficiencies during the survey, the accreditation for that location and/or the organization as a whole is reviewed by the Clinical Manager/designee and the Accreditation Review Committee. Following the review, the organization may be placed in Under Review.

F. Ownership or Ownership Information Change

1. The following process is followed when an organization has an ownership or ownership information change of 5% or greater, such as:
 - a. Stock transfer
 - b. Asset purchase
 - c. Acquisition
 - d. Merger
 - e. Consolidation
2. The following information is submitted to the organization's ACHC Account Advisor by the proposed new owner:
 - a. Letter of attestation that includes:
 - Type of change (acquisition, merger, etc.).
 - Detail of all changes, including new management and/or owner.
 - Proposed date of change.
 - Statement that policies and procedures are not changing, or, if they are changing, details on the specific changes.
 - Statement that the new owner has accepted the transfer of the seller's Medicare Provider Agreement (if applicable).
 - Lists of old and new federal tax ID numbers and NPI numbers (if applicable).
 - Who the new contacts will be, including the names of the owner, leader, liaison, and the phone numbers and email addresses for each.
 - b. Documentation that includes:
 - Completed CHOW form. The organization should complete and submit the "Change of Ownership" form, which can be downloaded from Customer Central on the ACHC website. (The form is located under the "Forms" header. To download, select "Change of Ownership Request Form – Home Infusion Therapy." This form also can be completed electronically using an e-signature.)

- Proof that the new owners/managers/agency are not on the OIG exclusion list.
 - Pre-transaction and Post-transaction organizational charts.
 - Business/state licenses, if applicable.
 - Resumes of new manager/leader and owner.
- c. Organization should submit:
- Updated 855B form to CMS.
 - Upon receipt of the CMS acknowledgement letter, submit copy to ACHC.
3. A review of the documentation is performed and any missing information is requested from the organization in writing. ACHC holds the documentation without further processing until the missing information is received from the organization. Once all required documentation has been submitted, it is reviewed and an accreditation decision is made.
4. Upon approval of the submitted documentation, ACHC issues accreditation based on the date that all required documentation was submitted. All fees must be paid before approval documentation will be issued by ACHC.
5. If it is determined a survey is necessary, the normal unannounced survey scheduling process will apply and the organization will be charged a survey fee. If it is determined a survey is not necessary, the organization will be charged a fee as indicated in the Accreditation Agreement.
6. If the organization is found to have substantial deficiencies during the survey, a Plan of Correction will be required and/or a follow-up Focus Survey may be required.

IX. Public Information

A. Logo/Advertising Language

An organization must accurately describe only the program(s), service(s) and branch office(s) currently accredited by ACHC and abide by the ACHC Brand Guidelines when displaying accreditation status using ACHC's logos or ACHC's name. False or misleading advertising represents noncompliance with the ACHC Accreditation Process and will result in penalties up to and including termination of accreditation. The ACHC Brand Guidelines are available on the organization's Customer Central website. Branch programs and services accredited during the accreditation cycle cannot be advertised as accredited until appropriate accreditation certificates are issued by ACHC.

B. Press Releases

ACHC encourages organizations to publicize their accreditation status. Publicity tips and a sample press release are available to approved organizations on the Customer Central website.

X. Nonconformance Policy

A. Handling of Complaints

As required by ACHC Accreditation Standards, accredited organizations must provide ACHC's telephone number to their patients for purposes of reporting a complaint as part of their patient informational material. If complaints cannot be resolved through the organization's complaint process, patients may file a complaint with ACHC. These complaints should identify facts or circumstances that relate to the complaint. ACHC documents and investigates all complaints/allegations received against currently accredited organizations. ACHC follows CMS Complaint Procedure guidelines for

conducting investigations, and records of complaints are maintained. ACHC will investigate and maintain records on complaints from any source when an ACHC accredited organization appears to be out of compliance with its ACHC Accreditation Standards.

1. Complaint should include:
 - a. Name, mailing address and phone number of the person filing the complaint.
 - b. Name of the organization involved.
 - c. A detailed description of the incident that is the subject of the complaint, including identification of date, time and location of each incident, as well as the identity of other individuals with information about the incident.
2. While under investigation by ACHC, a complaint is a confidential matter. However, ACHC cannot guarantee complainants that their identity will remain confidential if the organization determines the identity based on their own internal methods/investigation.

B. Processing a Complaint

ACHC will determine the severity and urgency of the allegations so that appropriate and timely action can be taken. Comprehensive information is collected during the Intake Process. Quality Assurance or an appropriate designee enters pertinent information into the complaint database and then discusses the complaint with the appropriate Clinical Manager, who is professionally qualified to evaluate the allegations to ensure that patients are not in danger of abuse, neglect, exploitation, and inadequate care or supervision.

C. Immediate Jeopardy

Immediate Jeopardy (IJ) is defined as: "A situation in which the provider's noncompliance with one or more requirements of participation has caused, or is likely to cause, serious injury, harm, impairment, or death to a patient." (42 CFR Part 489.3) Complaints are assigned this priority if the alleged noncompliance indicates there was serious injury, harm, impairment or death of a patient or resident, or the likelihood for such, and there continues to be an immediate risk of serious injury, harm, impairment or death of a patient or resident unless immediate corrective action is taken. The identification and removal of IJ, either psychological or physical, are essential to prevent serious harm, injury, impairment or death of individuals.

1. In accordance with the Medicare State Operations Manual Appendix Q, ACHC acknowledges the following principles of IJ, including:
 - a. Only one individual needs to be at risk. Identification of IJ for one individual will prevent risk to other individuals in similar situations.
 - b. Serious harm, injury, impairment or death does not have to occur before considering IJ. The high potential for these outcomes to occur in the very near future also constitutes IJ.
 - c. Individuals must not be subjected to abuse by anyone, including, but not limited to the organization's personnel, consultants or volunteers, and family members or visitors.
 - d. Serious harm can result from both abuse and neglect.
 - e. Psychological harm is as serious as physical harm.
 - f. When a Surveyor has established through investigation that a cognitively impaired individual harmed an individual receiving care and services from the organization

due to the organization's failure to provide care and services to avoid physical harm, mental anguish or mental illness, this should be considered neglect.

- g. Any time a team cites abuse or neglect, it should consider IJ.
- 2. ACHC will conduct an unannounced survey of the organization to investigate the issues within two business days of receipt of the allegations.
- 3. If IJ has been identified, a verbal notice is given to the entity, including the specific details and individuals at risk. If corrective measures have not already been implemented, the entity should begin immediate removal of the risk and immediately implement corrective measures to prevent repeat jeopardy situations. Only on-site observation of the entity's corrective actions justifies a determination that an IJ has been removed.
- 4. A formal written report is then prepared to reflect the above findings and it is submitted to ACHC within two business days of completion of the on-site review. Documentation is forwarded to and reviewed by the Clinical Compliance Department and Accreditation Review Committee, and a final report of findings is sent to the organization within 10 business days of completion of the on-site review.
- 5. Decision and Notification to Involved Parties
 - a. If, upon completion of the investigation of an organization, ACHC identifies an IJ situation, a condition-level deficiency is cited, and CMS is notified as applicable. The Board Chair and Executive Management are also immediately notified.
 - b. If sufficient evidence exists that the organization has violated ACHC Accreditation Standards, the organization may be placed Under Review.
 - c. If an organization's accreditation is terminated, ACHC will notify CMS, as applicable, of the termination. The organization will be removed from all listings of ACHC-accredited sites.

D. Non-Immediate Jeopardy – High

Complaints and/or incidents are assigned this priority if the alleged noncompliance with the applicable ACHC Accreditation Standard, if substantiated, would not represent an IJ, but would result in a determination of substantial noncompliance (i.e., at least one condition-level deficiency). An on-site survey is initiated within 45 calendar days of receipt of the complaint.

A formal written report is then prepared to reflect the above findings and submitted to ACHC within two business days of completion of the on-site review. Documentation is forwarded to and reviewed by the Clinical Compliance Department and Accreditation Review Committee, and a final report of findings is sent to the organization within 10 business days of completion of the on-site review.

E. Non-Immediate Jeopardy – Medium

Complaints and/or incidents are assigned this priority if the alleged noncompliance caused or may cause harm that is of limited consequence and does not significantly impair the individual's mental, physical, and/or psychosocial status or function. The incident or complaint, if substantiated, would not result in a determination of substantial non-compliance (i.e., there would not be any condition-level deficiency). An on-site survey must be scheduled no later than when the next on-site survey occurs, or one year after receipt of the complaint and/or incident, whichever comes first.

F. Non-Immediate Jeopardy – Low

Complaints and/or incidents are assigned this priority if the alleged noncompliance may have caused physical, mental, and/or psychosocial discomfort that does not constitute injury or damage. In most cases, an investigation of the allegation can wait until the next on-site survey.

G. Administrative Review/Offsite Investigation

This priority is used for complaints and/or incidents triaged as not needing an on-site investigation initially. This determination can be made through investigative action (written/verbal communication or documentation) initiated by ACHC to the provider to gather additional information that is adequate in scope and depth to determine that an on-site investigation is not necessary. ACHC has the discretion to review the information at the next on-site survey.

A fee will be processed for Administrative Review/Offsite Investigations requiring a Plan of Correction.

H. Referral – Immediate

This priority is used if the nature and seriousness of the complaint and/or incident or state/federal procedures require the referral or reporting of this information for investigation to another agency, without delay. This priority may be assigned in addition to one of the priorities listed above.

I. Referral – Other

Intakes are assigned this priority when referred to another agency or board for investigation or for informational purposes. This priority may be assigned in addition to one of the priorities listed above.