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ACCREDITATION
BOARD

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ACCREDITATION PROCESS

 PHARMACY



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 seeking Pharmacy Compounding Accreditation Board (PCAB) accreditation for non-sterile and sterile pharmacy compounding, 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. Eligibility Requirements

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

The organization must:

1. Be licensed according to applicable state and federal laws and regulations and maintain all current legal authorization to operate.
2. Occupy a building in which services are provided/coordinated that is identified, constructed, and equipped to support such services.
3. Submit all required documents and fees to ACHC within specified time frames.
4. ACHC reserves the right to review, and at its sole discretion, reject the application of pharmacies that:
 - a. Have outstanding FDA 483 inspection reports or warning letters, or;
 - b. Are placed on probation (also called "terms and conditions") by a state Board of Pharmacy for any grounds related to compounding pharmacy services, client/patient or public safety, or controlled substances violations.

B. Accreditation Services

1. **Sterile Pharmacy Compounding, ref. USP <797> (CFST):** Sterile Pharmacy Compounding is the practice of preparing sterile medications for clients/patients through strict procedures to prevent contamination and maintain client/patient safety. ACHC Accreditation for Sterile Pharmacy Compounding measures a specific set of process standards that concentrate on the quality and consistency of medications that are produced.
2. **Non-Sterile Pharmacy Compounding, ref. USP <795> (CFNS):** Non-Sterile Pharmacy Compounding is a process by which a pharmacist prepares drugs by combining, mixing, or altering ingredients into a pharmaceutical preparation. These preparations are designed to be administered by a route of administration that does not require sterility as result of a practitioner's prescription drug order.

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Compounding includes the preparation of drugs in anticipation of receiving prescription drug orders based on routine, regularly observed prescribing patterns.

NOTE: Organizations that offer both sterile and non-sterile compounding services at the same location must apply for accreditation for both services.

III. Principles Governing the Accreditation Survey

A. Compliance

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

- a. Review of Master Formulary Records
- b. Personnel files
- c. Policies and procedures
- d. Observations
- e. Interviews

It is the organization's responsibility to ensure compliance with the ACHC Accreditation Standards at all times during the accreditation period.

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 PCAB Standards for Accreditation or suggestions on how to implement them. During the survey, ACHC Surveyors will provide education and "best practice" suggestions to help the organization achieve optimum performance.

C. Types of Surveys

1. **Initial Accreditation Survey*:** An Initial Survey is conducted on organizations that apply for ACHC Accreditation for the first time. Initial Surveys are unannounced.
2. **Renewal Accreditation 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; however, during the Renewal Survey, the Surveyor also reviews previous deficiencies for compliance. Renewal Surveys are unannounced.
3. **Dependent Survey:** A Dependent Survey is a re-survey conducted on an organization that was not in compliance with ACHC Accreditation Standards. Dependent Surveys are unannounced.
4. **Focus Survey:** A Focus Survey is conducted on organizations to ensure ongoing and continued compliance with the ACHC Accreditation Standards. Focus Surveys can take place anytime throughout the accreditation period or for any organizational changes. Focus surveys are unannounced.
5. **Complaint Survey:** A Complaint Survey is conducted on organizations that have a complaint filed against them. Should ACHC determine during the investigation that a survey is required, ACHC will conduct a Complaint Survey. Complaint Surveys are unannounced.
6. **Disciplinary Action Survey:** A Disciplinary Action Survey is conducted on

organizations due to noncompliance from a previous survey, the ACHC Accreditation Standards and/or Accreditation Process and/or a breach in ACHC Accreditation Agreement. Disciplinary Action Surveys are unannounced.

7. **Virtual Survey*:** A Virtual Survey is conducted using a virtual hosting solution that allow 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 and Medicaid Services (CMS). Virtual surveys review the same material as on on-site survey, and the organization need to show compliance with all ACHC standards, state and federal requirements. Virtual surveys can be announced or unannounced depending on the program.

*** Full Survey:** This is a comprehensive survey examining all of the ACHC Accreditation Standards.

IV. Accreditation Process before the Survey

A. Register for access to ACHC through Customer Central

1. Access Customer Central through the ACHC website (www.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.
2. Once purchased, organization has unlimited access to all PCAB 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 non-refundable deposit (applied toward accreditation fee).

D. Execute Agreement for Accreditation Services

1. The Agreement for Accreditation Services and the Business Associate Agreement (BAA) outline the obligations of both ACHC and the organization.
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. Attestation on PER checklist is completed confirming existence of required policies and procedures.

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2. Upload required PER checklist 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 PER 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. (Please note, 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
4. 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. 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.

V. Accreditation Survey Process

A. Accreditation Survey Day

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 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:
 - i. Personnel record review
 - ii. Product record review
 - iii. Risk management
 - iv. Performance Improvement activities
 - v. Observations
 - vi. Personnel interviews
4. **Closing Conference**

During the closing conference the Surveyor discusses survey findings while the organization's personnel are given the opportunity throughout the survey to provide information that does not appear readily available to the Surveyor. The closing conference provides representatives of the organization a final opportunity to clarify information or present data that may not have been reviewed by the Surveyor during the survey. The Surveyor does not render judgment as to whether the organization will be granted accreditation. The Surveyor's role is to review information presented and to clarify, observe, and verify data that supports compliance with applicable ACHC Accreditation Standards.

B. 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

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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 is entered into an electronic tool that provides objective data for determining the accreditation decision.
2. **Preparing the Summary of Findings:** The Summary of Findings is prepared detailing all ACHC Accreditation Standards that were marked as deficiencies during the accreditation survey. Each ACHC Accreditation Standard marked as a deficiency will contain an "Action Required" statement. This will assist the organization in preparing a Plan of Correction to meet the ACHC Accreditation Standards. Surveyors may include any "Best Practice" suggestions in their summary as additional education. These best practice suggestions are not mandatory for the organization but are recommendations for improvement.
3. **Accreditation Review:** All Summary of Findings that result in a denial decision are analyzed through the clinical review process to ensure consistency before the denial decision is rendered.

B. Accreditation Decisions

1. Approval of Accreditation:

- a. Accreditation is Approved based on the following criteria:
 - i. Results of the data collected during survey
 - ii. Number and/or severity of deficiencies
 - iii. Clinical review process
- b. A Plan of Correction is required for any ACHC Accreditation Standards not fully met. The Plan of correction is due to ACHC within 30 days from the date of the organization's Approval letter with necessary supporting documentation.

- c. The Accreditation effective date for new and renewal organizations that receive an Approval of Accreditation is determined as follows:
 - i. **New Organization:** The accreditation effective date is the last day of survey.
 - ii. **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 prior to the expiration date. If the organization's survey took place after the expiration date, the approval date will start from the last date of survey.
- 2. Accreditation Pending:**
- a. Accreditation Pending is based on the following criteria:
 - i. Results of the data collected during survey
 - ii. Number and/or severity of deficiencies
 - iii. Clinical review process
 - b. A Plan of Correction is required for any standards not fully met. The Plan of Correction is due to ACHC within 30 days from the date of the organization's Accreditation Pending letter with necessary supporting documentation. Failure to submit requested evidence may result in the organization being designated as Under Review (Section VII, A).
 - c. All Plan of Correction s are reviewed through the clinical review process. After reviewing the Plan of Correction ACHC may:
 - i. Approve Plan of Correction and grant accreditation
 - ii. Reject Plan of Correction and require additional information
 - iii. Move an organization into Dependent Status (Section VI, B, 3)
 - d. Following the review of the Plan of Correction, if accreditation is granted, the effective dates for new and renewal organizations are determined as follows:
 - i. **New Organization:** The effective date is the day the approved Plan of Correction is received by ACHC. An approved Plan of Correction is one that has been accepted through the clinical review process.
 - ii. **Renewal Organization:** The Accreditation effective date will continue for an additional 36 months from the previous accreditation expiration date if the renewal survey and acceptable Plan of Correction is received prior to the expiration date. If the organization's survey takes place after the expiration date, the approval date will start from the date the acceptable Plan of Correction was received.
- 3. Dependent Status:**
- a. Dependent Status is determined based on the following criteria:
 - i. Results of the data collected during survey
 - ii. Number and/or severity of deficiencies
 - iii. Clinical review process
 - b. The Plan of Correction is due to ACHC within 30 calendar days from the date of the Dependent Status letter. The organization must submit written

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notification to ACHC of its readiness for a Dependent Survey, at the organization's expense, within 90 days of the date of the dependent letter. If the organization fails to notify ACHC within 90 days, the decision will move to a Denial of Accreditation.

- c. The Surveyor submits the findings from the Dependent Survey to the organization's Account Advisor and a decision will be made through the clinical review process. Upon review ACHC may:
 - i. Grant Accreditation
 - ii. Issue an Accreditation Pending
 - iii. Deny Accreditation (Section VI, B, 4)
- d. Following a Dependent Survey, if Accreditation is granted, the effective Accreditation dates for new and renewal organizations are determined as follows:
 - i. **New Organization:** 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 Plan of Correction is received by ACHC from the Dependent Survey. An approved Plan of Correction is one that has been accepted through the clinical review process.
 - ii. **Renewal Organization:** The accreditation effective date will continue for an additional 36 months from the previous accreditation expiration date if the Dependent Survey and an acceptable Plan of Correction is received prior to the expiration date. If the organization's survey takes place after the expiration date, the approval date will start from the date the acceptable Plan of Correction is received.

4. Denial of Accreditation:

- a. Accreditation is Denied based on the following factors:
 - i. Results of the data collected during survey
 - ii. Number and/or severity of deficiencies
 - iii. Clinical review process
- b. If Accreditation is Denied, the organization has the option to appeal the decision by following the steps outlined in the Appeals Process (Section VI, E)
- c. If Accreditation is Denied, the organization has the opportunity to re-apply for accreditation at any time they are ready for survey. At the time of re-application, a new application must be submitted with a non-refundable deposit and a PER. The organization has the option to submit a new PER or request that ACHC use the PER on file. If the organization elects to use the PER on file, it must notify the Account Advisor in writing. Upon receipt of an organization's application for survey as a result of a Denial of Accreditation, the application will be processed in the order it was received. ACHC does not expedite any part of the accreditation process for an organization that has received a Denial of Accreditation.

C. Accreditation Documentation

1. Once an accreditation decision is made through the clinical review process, the 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 with No Deficiencies:** Accreditation Approval letter, Certificate of Accreditation, state form, Summary of Findings, and window cling
 - b. **Approval of Accreditation with Deficiencies:** Accreditation Approval letter, state form, Summary of Findings, and Plan of Correction Template
 - i. Certificate of Accreditation and window cling will be sent to the organization when the completed Plan of Correction and evidence are approved by ACHC
 - c. **Accreditation Pending:** Accreditation Pending letter, state form, Summary of Findings, and Plan of Correction Template
 - i. Certificate of Accreditation and window cling will be sent to the organization when the completed Plan of Correction and evidence are approved by ACHC
 - d. **Dependent Status:** Dependent Status letter, Summary of Findings, and Plan of Correction Template
 - e. **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 through the clinical review process in order to be acceptable. The Plan of Correction 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 receives an Approval decision, the organization's Accreditation information can be found 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, they must follow the appeal process (refer to Section VI. E).

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 30 calendar days from the receipt of the Summary of Findings. Requests received after the 30 calendar day timeframe are not granted.

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2. The written request outlines the standard(s) noted in the Summary of Findings that the organization believes ACHC incorrectly determined as a deficiency. The organization must also provide evidence to support that, at the time of the survey, the organization was in compliance with the standard(s). 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 a dispute, ACHC sends an acknowledgement letter to the organization
4. If the organization is required to submit a Plan of Correction as a result of their survey, the organization must indicate on the Plan of Correction any standard(s) deficiency being disputed.
5. The ACHC Review Committee will evaluate and determine whether 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 refrains 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. Requests received after the 30 calendar day timeframe are not granted.
2. The written request outlines the standard(s) noted in the Summary of Findings that the organization believes ACHC incorrectly determined as a deficiency. The organization must also provide evidence to support that, at the time of the survey, the organization was in compliance with the standard(s). 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 sends an acknowledgement letter to the organization.
4. The ACHC Appeals Committee is 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 refrains from voting on the appeal.

6. Upon completion of the review, the ACHC Account Advisor notifies 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. PCAB Mid-Cycle 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 at any time during the accreditation period to ensure continued compliance with the ACHC Accreditation Standards.
2. Organizations that have been issued accreditation will be required to submit mid-cycle verification of compliance in accordance with standards TCRX7-A (non-sterile) and TCRX7-B (sterile). ACHC will review the submitted information for compliance with applicable standards, and deficiencies may require a Plan of Correction to be completed and approved. Failure to complete this process will place the organization's accreditation status Under Review (see section VII, A).

G. Renewing Accreditation

1. Accreditation is not automatically renewable. ACHC will issue the organization an updated Agreement for Accreditation Services. Once the agreement is executed, ACHC will put the organization into scheduling.
2. In the event an organization's accreditation expires, the organization's accreditation information will be removed from the accredited organization list located on the ACHC website.

VII. Disciplinary Actions

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

A. Noncompliance Process

1. The organization may be placed Under Review:
 - a. ACHC notifies customer
 - b. ACHC determines which of the following actions will be taken:
 - i. ACHC may request written documentation
 - ii. ACHC may conduct a Disciplinary Action Survey
 - iii. If ACHC determines that Immediate Jeopardy might be present, the process as described in Section X.C will be followed
 - iv. ACHC may require a Plan of Correction be completed
 - v. 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
 - i. Continuance of Accreditation

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- ii. Accreditation remains Under Review
 - iii. Termination
2. Accreditation may be terminated based on the number or severity of nonconformance or it is believed that compliance with ACHC standards is not possible within a reasonable timeframe.

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 clients/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 client/patient safety, public health or staff safety. Such an immediate threat can arise from one incident on a single occasion that affects a single client/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 client/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

ACHC requires organizations to provide the required documentation described below within 30 days of a change occurring. Changes include branch office addition or deletion, service addition or deletion, change in the name, location, ownership or control of the

organization. Failure to submit the required documentation within the 30 day timeframe may result in a gap in accreditation.

A. 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 Change of Name form that can be downloaded from Customer Central. The form is located under the "Forms" tab. Select "Name Change," then the corresponding Change of Name Request Form. This form 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. If it is determined a survey is necessary, the normal unannounced survey scheduling process will apply and the organization is 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 is reviewed through the clinical review process. Following the review, the organization may be placed in Under Review.

B. Location Change

1. If an organization goes through a location change, the organization must notify ACHC of the change within 30 days of the change. The organization should complete and submit the Change of Location form that can be downloaded from Customer Central. The form is located under the "Forms" tab. Select "Change of Location," then the corresponding Change of Location Request Form. The form 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 for any address changes outside the original city and state.
3. If it is determined a survey is necessary, the normal unannounced survey scheduling process will apply and the organization is 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 is reviewed through the clinical review process. Following the review, the organization may be placed in Under Review.

C. Cessation or Interruption within the Organization

1. If the organization has a cessation or interruption of all the organization's operations, offering 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 is placed in the

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organization's file. ACHC may request additional documentation before an acknowledgement letter is sent.

3. The organization notifies 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 PCAB Accreditation Standards.

D. Branch Office Addition

1. Any addition of a physical location added to an accredited provider must go through the branch addition process. The organization must complete and submit a Branch Addition Packet. The packet is located on Customer Central under the "Forms" tab and can be downloaded. The PCAB Branch Addition Packet must be completed in full, including all sections and any additional documentation 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 appropriate Clinical Manager/designee reviews the submitted documentation and a decision is made whether a survey is warranted. All branch additions with clean rooms will require a survey, prior to the issuance of accreditation.
3. Upon approval of the submitted documentation, ACHC issues accreditation based on the date that all required documentation was submitted or if a survey is required it is the date an approved Plan of Correction was received. ACHC will not back date 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 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.

E. Service Addition

1. Organizations that request to add a new service to an already accredited program must complete and submit a Service Addition Packet. The packet can be downloaded from Customer Central and is located under the "Forms" tab. Select "Change Services," then the corresponding Service Addition Packet. The PCAB Service Addition Packet must be completed in full, including all sections and any additional documentation listed on the form.
2. A review of the documentation is performed and any missing information is requested from the organization in writing. ACHC holds the service addition documentation without further processing until the missing information is received from the organization. Additional information may be requested prior to approving the service addition. Once all required documentation has been

submitted, the appropriate Clinical Manager/designee reviews the submitted documentation and a decision is made whether a survey is warranted. All service additions with clean rooms will require a survey, prior to the issuance of accreditation.

3. Upon approval of the submitted documentation, ACHC issues accreditation based on the date that all required documentation was submitted or if a survey is required it is the date an approved Plan of Correction was received. ACHC will not back date an accreditation for any service addition. 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 is charged a survey fee. If it is determined a survey is not necessary, the organization will be charged the service addition fee 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. Merger/Ownership Changes

1. The following process is followed when an organization has a merger/ownership change, 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 for review through the clinical review process. Organizations are to report any ownership changes of 5% or greater.
 - a. Letter of attestation which includes:
 - i. Type of change (e.g., acquisition, merger, etc.)
 - ii. Detail of all changes including new management and/or owner
 - iii. Actual or anticipated date of change
 - iv. Statement that policies and procedures are not changing, or, if they are changing, what are the specific changes
 - v. List old and new federal tax ID number and NPI number, if applicable
 - vi. Who the new contacts will be, including: owner; leader; liaison; and the phone numbers and email addresses for each
 - b. Documentation that includes:
 - i. Completed site information form
 - ii. Pre-transaction and post-transaction organizational chart
 - iii. State Licensure Verification form

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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, the submitted documentation is reviewed and an accreditation decision is made whether a survey is warranted.
4. Upon approval of the submitted documentation, ACHC issues accreditation based on the date that all required documentation was submitted. If the documentation is submitted prior to the effective date, the approval date will begin on the date of the change. All fees must be paid in full before ACHC issues any accreditation documentation.
5. If it is determined a survey is necessary, the normal unannounced survey scheduling process will apply and the organization is charged a survey fee. If it is determined a survey is not necessary, the organization will be charged the fee indicated in the Accreditation Agreement.
6. 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 through the clinical review process. Following the review, the organization may be placed in Under Review.

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 Logo Usage 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 Logo Usage Guidelines are available on the organization's Customer Central website. Branch additions, program additions, and service additions cannot be advertised as ACHC accredited until accreditation is granted and 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 clients/patients as part of their client/patient informational material for purposes of reporting a complaint. If complaints cannot be resolved through the organization's complaint process, clients/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 clinical personnel with the professional qualifications to evaluate the allegations to ensure that clients/patients are not in danger of abuse, neglect, exploitation, and inadequate care or supervision.

C. Immediate Jeopardy (IJ)

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 client/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 client/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 client/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.

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- 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 Immediate Jeopardy 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 onsite observation of the entity's corrective actions justifies a determination that an Immediate Jeopardy has been removed.
4. A formal written report is then prepared to reflect the above findings and submitted to ACHC within two business days of completion of the onsite 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 ten business days of completion of the onsite review.
5. Decision and Notification to Involved Parties
 - a. If upon completion of the investigation of a deemed organization, ACHC identifies an IJ situation, 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 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 onsite review. Documentation is forwarded to and reviewed by the Clinical Compliance Department and Accreditation Review Committee and final report of findings is sent to the organization within ten business days of completion of the onsite 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 onsite survey must be scheduled no later than when the next onsite 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 onsite survey.

G. Administrative Review/Offsite Investigation

This priority is used for complaints and/or incidents triaged as not needing an onsite 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 onsite investigation is not necessary. ACHC has the discretion to review the information at the next onsite 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.

NOTE: If Clinical Compliance determines that the complaint does not involve client/patient care and the appropriate investigative method is through a request to the organization for documents, rather than a site visit, then ACHC sends the organization a written or verbal request for documents, including specific due dates for documentation. This action may be completed by the Quality Assurance or Clinical Compliance Department.