PHARMACY COMPOUNDING ACCREDITATION BOARD

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POLICIES & PROCEDURES

[PHARMACY CERTIFICATION]

Certification Program for Canadian Compounding

NSTR—Non-Sterile Compounding (Ref. USP <795>)
STR—Sterile Compounding (Ref. USP <797>)

ACCREDITATION COMMISSION *for* HEALTH CARE

PHARMACY COMPOUNDING ACCREDITATION BOARD

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I. Introduction

The Accreditation Commission for Health Care International, Inc. (ACHC) is a not-for-profit corporation incorporated and existing under the Canada Not-for-profit Corporations Act, which is certified to ISO 9001:2008 standards. ACHC is governed by a volunteer Board of Commissioners (Board), which is composed of health care professionals and consumers. The policies and procedures contained in this document pertain to all organizations seeking Pharmacy Compounding Accreditation Board (PCAB) Certification for non-sterile and sterile pharmacy compounding, whether they are applying for Certification for the first time, renewing Certification, 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 PCAB Certification Policies and Procedures. Accordingly, ACHC's services will be furnished in accordance with the most current version of the PCAB Certification Policies and Procedures 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 Certification if the following eligibility requirements are met.

The organization must:

1. Be licenced according to applicable provincial 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 Health Canada inspection reports or warning letters, or;
    b. Have been placed on probation (also called "terms and conditions") by a provincial College of Pharmacy for any grounds related to compounding pharmacy services, patient or public safety, or controlled substances violations.

B. Certification Services

1. **Sterile Pharmacy Compounding, ref. USP <797> (STR):** Sterile Pharmacy Compounding is the practice of preparing sterile medications for patients through strict procedures to prevent contamination and maintain patient safety. PCAB Certification 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> (NSTR):** 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. 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 Certification for both services.

III. Principles Governing the Certification Survey

A. Compliance

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

- **a.** Review of Master Formula Records
- **b.** Personnel files
- **c.** Policies and procedures
- **d.** On-site observations
- **e.** Interviews

It is the organization's responsibility to ensure compliance with the PCAB Certification Standards at all times during the three year Certification period.

B. Education

While the organization is preparing for its survey, the organization's Account Advisor is available to provide assistance with the Certification process. Clinical Managers are available for interpretation of PCAB Certification 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 Certification Survey*:** An Initial Survey is conducted on organizations which apply for PCAB Certification for the first time. Initial Surveys are unannounced.
2. **Renewal Certification Survey*:** A Renewal Survey is conducted on organizations that are currently Certified 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 PCAB Certification Standards. Dependent Surveys are unannounced.
4. **Focus Survey:** A Focus Survey is conducted on organizations to ensure ongoing and continued compliance with the PCAB Certification Standards. Focus Surveys can take place anytime throughout the Certification 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 site visit is required, ACHC will conduct a Complaint Survey. Complaint Surveys are unannounced.
6. **Disciplinary Action Survey:** A Disciplinary Action Survey is conducted on

organizations that are placed Under Review (Section VII, A) due to non-compliance from a previous survey, the PCAB Certification Standards and/or these Policies and Procedures. Disciplinary Action Surveys are unannounced.

*** Full Survey:** This is a comprehensive survey examining all of the PCAB Certification Standards.

IV. Certification Process before the Survey

A. Download the PCAB Certification Standards on the ACHC International Website

B. Submit Certification Application to ACHC

C. Submit Non-Refundable Deposit

D. Execute Agreement for Certification Services

1. The Agreement for Certification Services outlines the obligations of both ACHC and the organization.
2. Sign and return the Agreement to ACHC within the specified time frames listed on the cover page.
3. Failure to meet any terms of the Agreement 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.
2. ACHC evaluates the content of all required documents and the surveyor will discuss any questions with the organization during the onsite visit.
3. A review of all Policies and Procedures related to the PCAB Certification 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 black-out days on which ACHC will not schedule a survey.
3. The following days do not need to be included in the organization's black-out days:
   a. New Year's Day
   b. Family Day
   c. Good Friday
   d. Easter Monday
   e. Victoria Day
   f. St. Jean Baptiste Day
   g. Canada Day
   h. Civic Holiday
   i. Labour Day
   j. Thanksgiving
   k. Remembrance Day

l. Christmas Day
m. Boxing 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. Organizations may postpone an ACHC survey as long as the ACHC surveyor has not begun to travel to the organization's location. Postponements must be requested in writing to the organization's Account Advisor using the ACHC Postponement Form. ACHC will invoice a postponement fee as listed in the Agreement for Certification Services.
2. The organization is responsible for notifying the Account Advisor in writing of its readiness for survey within 180 days from receipt of the ACHC Postponement Form. If the organization notifies the Account Advisor within the specified timeframes, the organization will be scheduled for a survey following the ACHC scheduling process. If the organization does not notify the Account Advisor within the specified timeframes, the organization's deposit will be forfeited, application voided, and the organization must re-apply for Certification.

V. Certification Survey Process

A. Certification 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 PCAB Certification Standards, the survey focuses on the following:
      i. Personnel record review
      ii. Product record review
      iii. Risk management
      iv. Performance Improvement activities
      v. Onsite 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 Certification. The surveyor's role is to review information presented and to clarify, observe, and verify data that supports compliance with applicable PCAB Certification Standards.

B. Refusal of Survey

1. Organizations have the right to refuse an ACHC survey. In the event a refusal is requested, the organization must speak to the Account Advisor or an appropriate manager at ACHC to request a Survey Refusal Form. A completed Survey Refusal Form must be submitted to ACHC before the surveyor can leave the location. If a surveyor arrives on-site and the organization does not meet the eligibility criteria for a Certification survey, the organization must refuse the survey and complete a Survey Refusal Form.
2. If an ACHC surveyor arrives on-site and the organization is not operating during its posted business hours, the surveyor will notify the ACHC Account Advisor and leave the location. This will be considered a refusal of survey.
3. The organization is charged a refusal fee as listed in the Agreement for Certification Services. The organization is responsible for notifying the Account Advisor in writing of its readiness for a resurvey following the timeframes as detailed in the Agreement for Certification Services. If the organization notifies the Account Advisor within the specified timeframes as detailed in the Agreement for Certification Services, the organization will be sent to scheduling and will follow the normal scheduling process. If the organization notifies the Account Advisor outside of the specified timeframes as detailed in the Agreement for Certification Services, the organization's deposit will be forfeited, application voided and the organization must re-apply for Certification.

VI. Certification Process Post Survey

A. Reviewing the Data Collected

1. **Scoring:** Following the conclusion of the Certification 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 which provides objective data for determining the Certification decision.
2. **Preparing the Summary of Findings:** The Summary of Findings is prepared detailing all PCAB Certification Standards that was marked as a deficiency during the Certification survey. Each PCAB Certification standard marked as deficient will contain an "Action Required" statement. This will assist the organization in preparing a Plan of Correction (POC) to meet the PCAB Certification 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. **Certification 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. Certification Decisions

1. **Approval of Certification:**
   a. Certification 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 (POC) is required for any PCAB Certification Standards not fully met. The POC is due to ACHC within 30 days from the date of the organization's Approval letter with necessary supporting documentation. A Certificate of Certification will not be sent to the organization until the Plan of Correction (POC) has been approved by ACHC.
   c. The Certification effective date for new and renewal organizations that receive an Approval of Certification is determined as follows:
      i. **New Organizations:** The Certification effective date is the last day of survey.
      ii. **Renewal Organization:** The Certification effective date will continue for an additional 12 months from the expiration if the organization shows proof of on-going compliance with the PCAB Certification Standards.
2. **Certification Pending:**
   a. Certification 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 (POC) is required for any standards not fully met. The POC is due to ACHC within 30 days from the date of the organization's Certification Pending letter with necessary supporting documentation. Failure to submit evidence may result in the organization being designated as Under Review (Section VII, A).
   c. All POCs are reviewed through the clinical review process. After reviewing the POC ACHC may:
      i. Approve POC and grant Certification
      ii. Reject POC and require additional information
      iii. Move an organization into Dependent Status (Section VI, B, 3)
   d. Following the review of the POC, if Certification is granted, the effective dates for new and renewal organizations are determined as follows:
      i. **New Organizations:** The effective date is the day the approved Plan of

Correction is received by ACHC. An approved POC is one that has been accepted through the clinical review process.

ii. **Renewal Organization:** The Certification effective date will continue for an additional 12 months from the expiration if the organization shows proof of on-going compliance with the ACHC Certification Standards.

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 POC is due to ACHC within 30 calendar days from the date of the Dependent Status letter. The organization must submit written notification to ACHC of its readiness for a Dependent Survey, at the organizations 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 Certification.
   - **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 Certification
     - **ii.** Issue a Certification Pending
     - **iii.** Deny Certification (Section VI, B, 4)
   - **d.** Following a Dependent Survey, if Certification is granted, the effective Certification dates for new and renewal organizations are determined as follows:
     - **i.** **New Organizations:** The effective date of Certification 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 Certification is the day the approved POC is received by ACHC from the Dependent Survey. An approved POC is one that has been accepted through the clinical review process.
     - **ii.** **Renewal Organization:** The Certification effective date will continue for an additional 12 months from the expiration if the organization shows proof of on-going compliance with the PCAB Certification Standards.

4. **Denial of Certification:**
   - **a.** Certification 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 Certification 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 Certification is Denied, the organization has the opportunity to re-apply for Certification 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 Certification, the application will be processed in the order it was received. ACHC does not expedite any part of the Certification process for an organization that has received a Denial of Certification.

C. Certification Documentation

1. Once a Certification decision is made through the clinical review process, the Certification decision is given to the Account Advisor. The Account Advisor then prepares the proper documentation to send to the organization.
2. Based on the Certification decision, the Account Advisor sends the following:
   a. Approval of Certification with No Deficiencies: Certification Approval letter, Certificate of Certification, Summary of Findings, and window decal
   b. **Approval of Certification with Deficiencies:** Certification Approval letter, Summary of Findings, and Plan of Correction Template
      i. Certificate of Certification and window decal will be sent to the organization when the completed POC and evidence is approved by ACHC
   c. **Certification Pending:** Certification Pending letter, Summary of Findings, and Plan of Correction Template
      i. Certificate of Certification and window decal will be sent to the organization when the completed POC and evidence is approved by ACHC
   d. **Dependent Status:** Dependent Status letter, Summary of Findings, and Plan of Correction Template
   e. **Denial of Certification:** Denial letter and Summary of Findings
3. The POC must be completed in its entirety, returned to ACHC and approved through the clinical review process 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 receives an Approval decision, the organization's Certification information can be found on the ACHC website for verification.

D. Dispute Process

Organizations, whether applying for the first time or renewing their Certification, 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.
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 (POC) as a result of their survey, the organization must indicate on the POC any standard(s) deficiency being disputed.
5. The ACHC Review Committee will evaluate and determine whether ACHC followed its stated Policies and Procedures in conducting the organization's Certification 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 Certification, may formally request to appeal a Denial decision. The procedure to appeal a Denial of Certification 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 Policies and Procedures in conducting the organization's Certification survey.
5. Any ACHC Appeals Committee member who has a conflict of interest with the organization under review is prohibited 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. Continued Compliance

1. Certification is contingent upon continued compliance with the PCAB Certification Standards and the Certification Policies and Procedures. After an organization is granted Certification, ACHC reserves the right to make unannounced Focus Survey visits at any time during the Certification period to ensure continued compliance with the PCAB Certification Standards.
2. Organizations that have been issued Certification will be required to submit annual verification of compliance. ACHC will review the submitted information and will make the determination whether Certification will continue for an additional 12 months.

G. Renewing Certification

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

VII. Disciplinary Actions as a Result of Survey Findings

Disciplinary actions can result as a consequence to one of the following: Dependent Survey, Focus Survey, Complaint Survey, Change of Ownership (CHOW) Survey and/or any failure to remain in compliance with the PCAB Certification Standards or these Policies and Procedures. The organization may be billed for surveys conducted which resulted in a disciplinary action. The following disciplinary action statuses are possible:

A. Under Review

1. The organization's Certification can be placed Under Review when ACHC has sufficient evidence that non-compliance with the PCAB Certification Standards and/or these Policies and Procedures has occurred. In particular, ACHC will review the nature, severity, and scope of the non-compliance and the degree of harm or potential for harm to patients. ACHC also will review the organization's service performance, prior history of compliance with the PCAB Certification Standards and/or these Policies and Procedures.

2. The organization is required to formulate and return a Plan of Correction for deficiencies within 10 calendar days of the notification letter. The Review Committee will review the submitted documentation and render a decision on whether to continue or terminate the organization's Certification. A Disciplinary Action Survey may be required to ensure that all corrective actions have been initiated.

B. Termination

Following a status of Under Review, ACHC will determine if an organization's Certification will be terminated. Termination entails loss of an organization's Certification and may include notification to the appropriate regulatory agencies including CMS. Organizations may apply for Certification when they feel ready. Termination decisions are considered public record and will be reported to all appropriate parties. The organization will be removed from all listings of ACHC Certified sites.

VIII. Notification of Changes

ACHC requires organizations to provide the required documentation described below within thirty (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 thirty (30) day timeframe may result in disciplinary action including, being placed Under Review or a loss or suspension of an organization's Certification.

A. Name Changes

1. If an organization goes through a name change, the organization must notify ACHC of the change via a notification letter and additional documentation. The organization's notification letter and additional documents must include the following:
   a. Effective date of the change
   b. Former name, as well as new legal name
   c. Photographs of the following:
      i. Outside of building with signage with new name
      ii. Posted hours of operation
      iii. Interior office and/or retail space
      iv. Warehouse (if applicable)
   d. Include copies of all licences with new name
2. ACHC may request additional documentation upon review. If approved, ACHC will issue a new Certification certificate.
3. If it is determined a site 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 prorated fee based on the length of remaining Certification.
4. If the organization is found to have substantial deficiencies during the site survey, the Certification 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 via a notification letter and additional documentation. The organization's notification letter and additional documents must include the following:
   a. Effective date of the change
   b. Former address and new address
   c. Photographs of the following:
      i. Outside of building with signage
      ii Posted hours of operation
      iii. Interior office and/or retail space
      iv. Warehouse (if applicable)
   d. Include copies of all licences with new address
2. ACHC may request additional documentation upon review. If approved, ACHC will issue a new Certification certificate for any address changes outside the original city and province.
3. If it is determined a site 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 prorated fee based on the length of remaining Certification.
4. If the organization is found to have substantial deficiencies during the site survey, the Certification 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 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 Certification, 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 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 Certification status and determine if a site visit is required to ensure compliance with the PCAB Certification Standards.

D. Branch Office Addition

1. Any addition of a physical location added to a Certified provider must go through the branch addition process. The organization must submit the following:
   a. Branch Addition Checklist Form with signed attestation statement
   b. ACHC Additional Site Information Form
   c. Licencure Verification Form and copies of applicable licences for each province checked
   d. Copies of most recent licences for professionals requiring licencure (example Pharmacist, Pharmacy Technician), if applicable
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.
3. ACHC conducts an onsite survey for all Branch Additions. Upon approval of the onsite survey, ACHC issues Certification based on the survey findings. ACHC will not back date a Certification for any organization that sends notification after the branch opening. All fees must be paid in full before ACHC issues any Certification documentation.
4. If the organization is found to have substantial deficiencies during the site survey, the Certification for that location and/or the organization as a whole is reviewed by the Clinical Manager/designee and the Certification Review Committee. Following the review, the organization may be placed Under Review.

E. Service Addition

1. Organizations that request to add a new service to an already Certified program must submit the following:
   a. Service Addition Checklist Form with signed attestation statement
   b. Licencure Verification Form and copies of applicable licences for each state checked
   c. Policies and procedures for added service
   d. List of all appropirate licence numbers and/or certification of staff, if applicable
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. Once all required documentation has been submitted, the appropriate Clinical Manager/designee reviews the submitted documentation and a Certification decision is made whether a site survey is warranted. A site survey is based on several factors that include the original survey findings, where the organization is in the three year Certification cycle, and how many locations have been added from the start of its Certification.
3. Upon approval of the submitted documentation, ACHC issues Certification based on the date that all required documentation was submitted if a site visit is not required. ACHC will not back date a Certification for any service addition. If it is

determined a survey is not necessary, the organization is charged a prorated fee based on the length of remaining Certification. All fees must be paid in full before ACHC issues any Certification documentation.

4. If it is determined a site survey is necessary, the normal unannounced survey scheduling process will apply and the organization is charged a survey fee. A Certification decision will not be issued until the site visit is completed. All fees must be paid in full before ACHC issues any Certification documentation.
5. If the organization is found to have substantial deficiencies during the site survey, the Certification for that location and/or the organization as a whole is reviewed by the Clinical Manager/designee and the Certification Review Committee. Following the review, the organization may be placed Under Review.

F. Ownership or Ownership Information Changes

1. The following process is followed when an organization has an ownership or ownership information 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 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. Proposed date of change
        - iv. Statement that policies and procedures are not changing, or, if they are changing, what the specific changes are
        - v. List of the organization's new CRA Business Number and any new provincial healthcare billing numbers
        - vi. Who the new contacts will be, including: owner; leader; liaison; and the phone numbers and email addresses for each
    - b. Documentation which includes:
        - i. New organizational chart
        - ii. Copy of the bill of sale
        - iii. Copies of all applicable Licences
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 a Certification decision is made whether a site survey is warranted.

4. Upon approval of the submitted documentation, ACHC issues Certification 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 Certification documentation.
5. If it is determined a site 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 prorated fee based on the length of remaining Certification.
6. If the organization is found to have substantial deficiencies during the site survey, the Certification 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 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 Certified by ACHC and abide by the ACHC Logo Usage Guidelines when displaying Certification status using ACHC's logos or ACHC's name. False or misleading advertising represents noncompliance with PCAB Certification Policies and Procedures and will result in penalties up to and including termination of Certification. The ACHC Logo Usage Guidelines are available on the organization's Customer Central website. Branch programs and services accredited during the Certification cycle cannot be advertised as accredited until appropriate Certification certificates are issued by ACHC.

B. Press Releases

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

X. Nonconformance Policy

A. Handling of Complaints[1]

As required by PCAB Certification Standards, Certified organizations must provide ACHC's telephone number to their clients/patients/customers as part of their informational material for purposes of reporting a complaint. If complaints cannot be resolved through the organization's complaint process, these individuals 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 Certified organizations. ACHC will investigate and maintain records on complaints from any source when an ACHC Certified organization appears to be out of compliance with its PCAB Certification 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 patients are not in danger of abuse, neglect, exploitation, 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 patient." 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 for individuals.

1. 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, 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 on 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 Certification 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 ACHC identifies an IJ situation, ACHC shall immediately notify the organization and all applicable regulatory authorities
   b. If sufficient evidence exists that the organization has violated PCAB Certification Standards, the organization may be placed Under Review.
   c. If an organization's Certification is terminated, the organization will be removed from all listings of ACHC Certified sites.

D. Non-Immediate Jeopardy – High

Complaints and/or incidents are assigned this priority if the alleged noncompliance with the applicable PCAB Standard, if substantiated, would not represent an IJ, but would result in a determination of substantial noncompliance. In these cases, an onsite survey is initiated within 45 calendar days of receipt of the compliant.

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 Certification 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. 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. This determination can be made through investigative action (written/verbal communication or documentation) initiated by ACHC to the organization 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.

H. **Referral – Immediate**

This priority is used if the nature and seriousness of the complaint and/or incident or Provincial/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 the Clinical Compliance Department determines that the complaint does not involve 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 Department or Clinical Compliance Department.

[1] http://www.cms.gov/Regulations-and Guidance/Guidance/Manuals/downloads/som107ap_q_immedjeopardy.pdf