



ACHC PROCESS COMPOUNDING INSPECTION



THOROUGH
INSPECTIONS



INDUSTRY
EXPERTS

ACCREDITATION COMMISSION *for* HEALTH CARE

aisinspections.org

Table of Contents

I. Introduction..... 3

II. Eligibility Requirements..... 3

III. Principles Governing the ACHC Inspection Services for Compounding 3

 A. Compliance 3

 B. Types of Inspections 3

IV. Pre-Inspection Process 3

 A. Pharmacy Completes AIS Inspection Application..... 3

 B. Pharmacy Submits AIS Inspection Application..... 4

 C. Pharmacy Signs Agreement for Pharmacy Inspection and Business Associate Agreement 4

 D. Pharmacy Submits Payment..... 4

 E. State Pharmacy Board Notification..... 4

V. Inspection Process..... 4

 A. Opening Conference..... 4

 B. Conduct Inspection 4

 C. Closing Conference..... 4

VI. Post-Inspection Process..... 5

 A. Inspection Data Submission 5

 B. Report Sent to Pharmacy and/or Recipients 5

I. Introduction

Accreditation Commission for Health Care (ACHC) is an independent, 501(c)(3) nonprofit accrediting organization whose Quality Management System 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 ACHC Inspection services (AIS) Process for Compounding Pharmacy Inspections contained in this document pertains to organizations applying for pharmacy inspections related to compounding practices. 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 this process. Accordingly, ACHC's services will be furnished in accordance with the most current version of the AIS Process for Compounding Pharmacy Inspections in effect on the date of the inspection or in effect at the time of any other activity.

II. Eligibility Requirements

The pharmacy may apply for an AIS Inspection for sterile or non-sterile compounding if the following eligibility requirements are met.

The pharmacy must:

- Be currently operating within the United States.
- Be licensed in its resident state.
- Be engaged in the business of providing compounding services for at least 30 days.
- Any other requirements as set forth by the agency for which the inspection is being conducted.

III. Principles Governing the ACHC Inspection Services for Compounding

A. Compliance

During the inspection, ACHC determines whether the pharmacy is compliant with AIS Inspection Criteria.

B. Types of Inspections

1. Initial Inspection: An initial inspection is conducted on pharmacies that apply for an inspection for the first time.
2. Renewal Inspection: A renewal inspection is conducted on pharmacies that apply for subsequent inspections.
3. Follow-Up Inspection: A follow-up inspection is conducted on pharmacies that demonstrate significant deficient practices and/or noncompliance with AIS Inspection criteria.

IV. Pre-Inspection Process

- A. Pharmacy completes AIS Inspection Application.

- B. Pharmacy submits AIS Inspection Application.
- C. Pharmacy signs Agreement for Pharmacy Inspection and Business Associate Agreement (BAA).
- D. Pharmacy submits payment
 - 1. Inspections are scheduled to occur within 60 days of receipt of the signed Agreement for Pharmacy Inspection.
 - 2. ACHC will provide to pharmacies a date range of no less than two weeks during which time the inspection will occur. The actual date of the inspection will not be provided to the pharmacy.
 - 3. ACHC will not conduct inspections on the following 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
- E. State Pharmacy Board Notification
 - 1. ACHC emails the Board of Pharmacy of the state in which the inspection will occur, regarding the upcoming inspection date and time. This gives the State Inspector the opportunity to accompany ACHC on-site.

V. Inspection Process

- A. Opening Conference

The opening conference may consist of the following based on the organizational structure:

 - 1. Introduction of the Inspector.
 - 2. Review of the tentative schedule.
 - 3. Review questions on any documents from the application process.
 - 4. Q & A from the organization about the inspection.
- B. Conduct Inspection
 - 1. The pharmacy authorizes ACHC to access the records and facilities that are necessary to ascertain compliance with the inspection. ACHC complies with all Health Insurance Portability and Accountability Act (HIPAA), privacy, and security regulations.
 - 2. The Inspector's role is to review information presented and to clarify, observe, and verify data that supports compliance.
- C. Closing Conference

The Inspector conducts a closing conference with the pharmacy's representatives. This allows a final opportunity to clarify information or present data that may not have been reviewed by the Inspector.

VI. Post-Inspection Process

A. Inspection Data Submission

Following the conclusion of inspection, the Inspector submits all of the data collected to ACHC for processing.

B. Report Sent to Pharmacy and/or Recipients

An electronic copy of the Inspection Report and other relevant supporting documentation are forwarded to the pharmacy and any intended recipients within 10 business days from the conclusion of the inspection.