



POLICIES & PROCEDURES COMPOUNDING INSPECTION



THOROUGH
INSPECTIONS



INDUSTRY
EXPERTS



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I. Introduction

Accreditation Commission for Health Care (ACHC) is an independent, 501(c)(3) non-profit accrediting organization, whose Quality Management System is certified to ISO 9001:2008 standards. ACHC is governed by a volunteer Board of Commissioners (Board), that is composed of healthcare professionals and consumers.

The ACHC Inspection services (AIS) Policies and Procedures for Compounding contained in this document pertain to organizations applying for pharmacy inspection 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 these AIS Policies and Procedures. Accordingly, ACHC's services will be furnished in accordance with the most current version of the AIS Policies and Procedures 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 On-Site Inspection:** An initial on-site inspection is conducted on pharmacies that apply for an Inspection for the first time.
2. **Renewal On-Site Inspection:** A renewal on-site inspection is conducted on pharmacies that apply for subsequent inspections.
3. **Follow-Up On-Site Inspection:** A follow-up on-site 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. On-site inspections are scheduled to occur within sixty (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 on-site 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

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

Final reports including an electronic copy of the Inspection Report, as well as other relevant supporting documentation, are forwarded to the pharmacy and any intended recipients within 10 business days from the conclusion of the inspection.