



Achieving PCAB Accreditation







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Associate Director, Education & Training



ACHCU

TOOLS

Workbooks Readiness Policy & Procedure Manuals Performance Improvement (PI) Audit Tools

EDUCATION

Workshops Webinars Training HealthTrainU

Education

Gap Analysis Compliance Audits Pre-Survey Prep

Customer Centered





Jon Pritchett,
PHARM.D., RPH., BCSCP
Program Director



Learning Objectives

- Review the Application Process
- Discuss PCAB Standards Updates
- Become familiar with the initial and renewal accreditation process
- Learn how to prepare an organization for the accreditation survey
- Get a detailed look at the survey day and post-survey process
- Learn how to utilize the ACHC Accreditation Guide to Success to ensure ongoing compliance



ACHC Accreditation Guide to Success

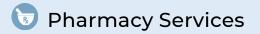
- ACHC Accreditation Guide to Success for PCAB
- Developed to help walk you through the accreditation process
- Gap analysis tools to help you assess readiness
- Surveyor hints regarding common deficiencies
- Sample forms and document templates





PCAB Accreditation

- Can additional accreditations be combined with PCAB?
- How does ACHC Inspection Services (AIS) compare with accreditation?
- Who now requires accreditation?



Ambulatory Infusion Center

Infusion Nursing

Infusion Pharmacy

Specialty Pharmacy

SRX without DMEPOS

Long Term Care Pharmacy

Mail Order Pharmacy

PCAB Accreditation

Non-Sterile Compounding (Ref. USP <795>)

Sterile Compounding (Ref. USP <797>)

ACHC Inspection Services

Distinctions*

Distinction in Oncology

Distinction in Hazardous Drug Handling (Ref. USP <800>)

Distinction in Infectious Disease Specific to HIV

Distinction in Nutrition Support





Distinction in Hazardous Drug Handling



DISTINCTION IN HDH





Current Offerings

Available Programs

- ACUTE CARE HOSPITAL (HFAP)
 - AMBULATORY CARE
- AMBULATORY SURGERY CENTER (HEAP)
 - ASSISTED LIVING
 - BEHAVIORAL HEALTH
 - CRITICAL ACCESS HOSPITAL (HEAP)
 - - DENTISTRY
 - **DMEPOS**
 - **HOME HEALTH**

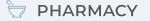












PRIVATE DUTY

RENAL DIALYSIS

SLEEP

STERILE COMPOUNDING (PCAB)



Current Offerings

Distinctions

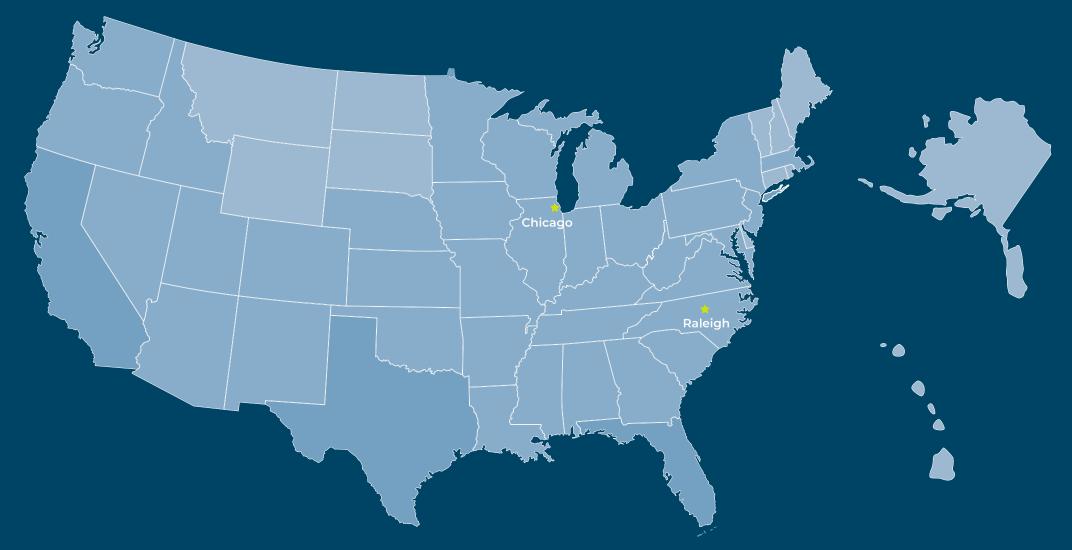
- TELEHEALTH
- T HAZARDOUS DRUG HANDLING
 - ▼ CUSTOM MOBILITY
- □ CLINICAL RESPIRATORY PATIENT MANAGEMENT
 - ▼ INFECTIOUS DISEASES SPECIFIC TO HIV
 - RARE DISEASES & ORPHAN DRUGS
 - ▼ NUTRITION SUPPORT
 - □ ONCOLOGY
 - ▼ PALLIATIVE CARE

Certifications (HFAP)

- □ JOINT REPLACEMENT
 - LITHOTRIPSY
 - STROKE
 - **Q** WOUND CARE



ACHC currently accredits 19,172 locations nationwide.





About ACHC

- Nationally recognized accreditation organization with more than 30 years of experience
- CMS Deeming Authority for Home Health, Hospice, Renal Dialysis, DMEPOS, Home Infusion Therapy, Clinical Laboratory, Acute Care Hospital, Critical Access Hospital and Ambulatory Surgery Center
- Recognition by major third-party payors
- Approved to perform state licensure surveys
- Quality Management System that is ISO 9001:2015 Certified



Experience the ACHC Difference

- Standards created for providers, by providers
- All-inclusive pricing no annual fees
- Personal Account Advisors
- Commitment to exceptional customer service
- Surveyors with industry-specific experience
- Dedicated clinical support
- Dedicated regulatory support
- Educational resources



ACHC Mission & Values

Our Mission

 Accreditation Commission for Health Care (ACHC) is dedicated to delivering the best possible experience and to partnering with organizations and healthcare professionals that seek accreditation and related services.

Our Values

- Committed to successful, collaborative relationships
- Flexibility without compromising quality
- Each employee is accountable for his or her contribution to providing the best possible experience
- We will conduct ourselves in an ethical manner in everything we do







Getting Started

Application Overview, Downloading Standards, & PER Process





Pharmacy Accreditation

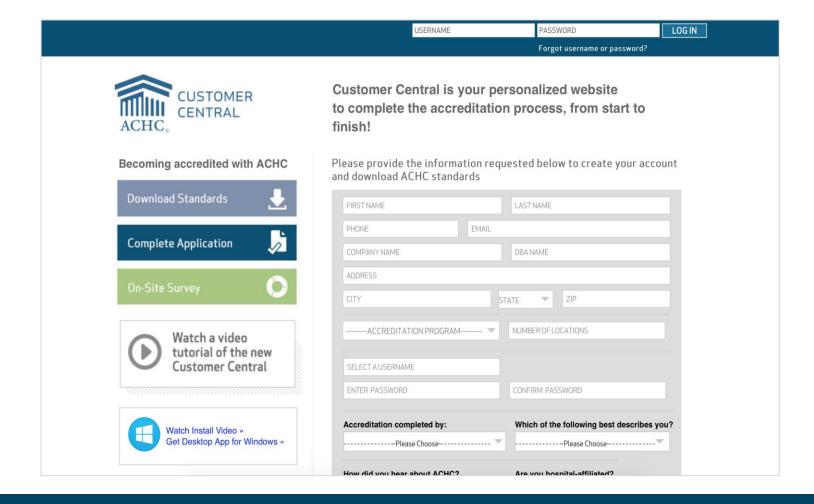
All ACHC Pharmacy Accreditation programs are based on patientspecific prescriptions.

- ACHC only evaluates and accredits on the basis of a patient-specific prescription.
- Pharmacies can only claim accreditation for those medications compounded on the basis of a patient-specific prescription.
- The Drug Quality and Security Act (DQSA) requires 503B registration and current good manufacturing practices (cGMP) compliance for sterile medications dispensed without a patient-specific prescription.



Registration

Customer Central: cc.achc.org

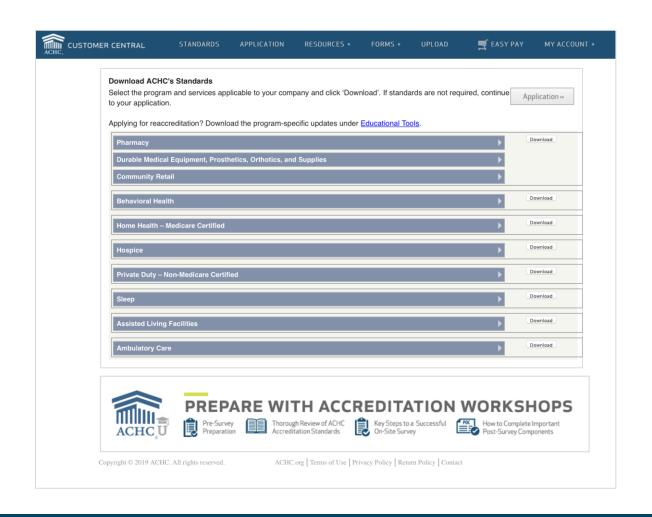






Standards

- Only download the services for which you want to be accredited
- Unlimited downloads
- Updates will be posted on cc.achc.org
- May add other services





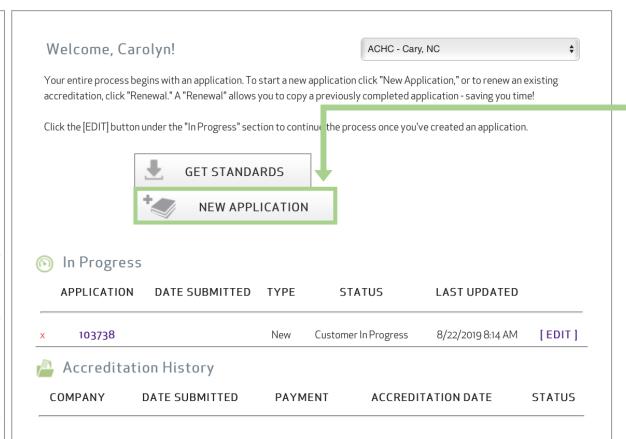


Account Advisor



- Nora Lee Stephen nstephen@achc.org (919) 785-1214 ext. 230 Fax: (919) 785 - 3011
- ACHC 139 Weston Oaks Ct. Cary, NC 27513
- Video Tutorials
 Customer Central Tour
 Application Tour
 PER "How To"
 On-Site Survey
 POC "How To"





If this is your first time with ACHC accreditation, click the "NEW APPLICATION" button.







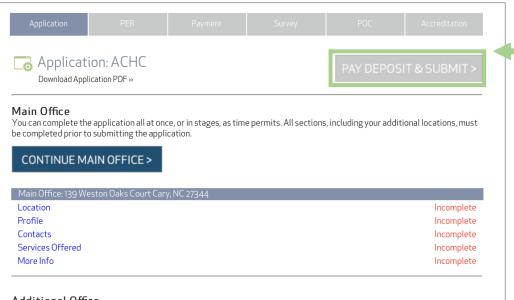


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Video Tutorials Customer Central Tour Application Tour PER "How To" On-Site Survey POC "How To"





Additional Office

Click the "ADD LOCATION" button to add other physical offices or warehouses.

+ ADD LOCATION

When the application is submitted, you will be prompted to complete the deposit payment.

ACHC accepts both credit cards and checks.





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+ ADD LOCATION

Each transaction will display a receipt. Click "Download Receipt PDF" save a PDF copy.



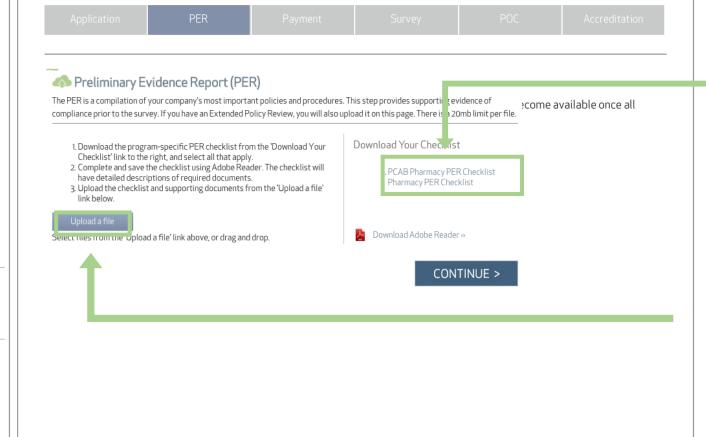


UPLOAD

Account Advisor



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- Video Tutorials Customer Central Tour Application Tour PER "How To" On-Site Survey POC "How To"







First, download the correct PER

Completely fill

out the PER

upload with

supporting

documents.

checklist and

checklist.



PCAB PRELIMINARY EVIDENCE REPORT (PER) INITIAL CHECKLIST



This checklist constitutes the requirements of the PER, which is mandatory for organizations applying for Pharmacy Compounding Accreditation Board (PCAB) Accreditation for Sterile and/or Non-Sterile Pharmacy Compounding.

Review and acknowledge that all of the following requirements have been met and submit this signed checklist with the required items listed below.

- Accreditation application
- Non-refundable deposit
- Current pharmacy License in home state
- Organizational chart
- Sample of Master Formulation Record
- Policies and procedures for the following:
 - Standard TCRX5-E
 - Standard TCRX5-G
 - Standard TCRX6-P (Non-Sterile Compounding)
 - Standard TCRX6-Q (Sterile Compounding)
 - Standard TCRX6-O (Sterile Compounding)

Disclosure of Pharmacy Citations (check only one):

- The facility is not currently under citation by any federal/state regulatory authority (FDA, Board of Pharmacy, etc.)
- Citation(s) by any federal/state regulatory authority were previously submitted by the facility with the application
- I am submitting with this PER Checklist citation(s) by federal/state regulatory authority(s)

Confirmation of the following (initial in spaces provided):

I attest that this organization possesses all policies and procedures as required by the Accreditation Standards
I acknowledge that this organization was/is/will be in compliance with the Accreditation Standards as of
(date)







Extended Policy Review

- Optional review of complete policies and procedures by an ACHC Surveyor to determine compliance prior to the on-site survey
- Feedback from an ACHC Surveyor regarding the alignment of agency's policies and procedures to ACHC Accreditation Standards
- Option to purchase through the Customer Central portal
- Customized Reference Guide for Required Documents; policies and procedures available as a download

Agreement

Accreditation Agreement (BAA/Contract) reviewed by customer, signed and returned to Account Advisor



14 Calendar Days

Payment Information
Deposit Received: </td
Discount (if applicable): << <insert amount="" discount="" here="">>></insert>
Remaining Balance: << <remaining balance="">>>></remaining>
<> <first payment="">>>> Due on line upon execution of this Agreement.</first>
<> <second payment="">>>> Due 12 months from date of the Accreditation Decision Letter.</second>
<> <third payment="">>>> Due 24 months from date of the Accreditation Decision Letter.</third>
Payment Method:
I wish to pay my bill online (an email with a link to online payment will be sent following the execution of this agreement
☐ I wish to receive a paper invoice for payment



So, when am I officially "in process?"

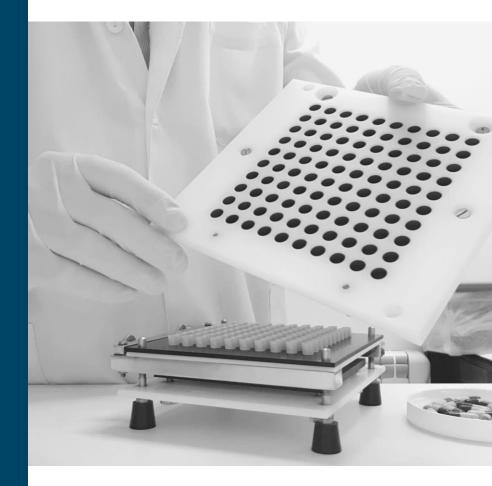
- Complete online application
- Submit deposit (online)
- Complete and return PER (online)
- Return signed Accreditation Agreement
- When will your survey be scheduled?
 - New application: Some point after "Date of Readiness" (excluding blackout dates)
 - Renewal: Based on when you apply, and when accreditation expires



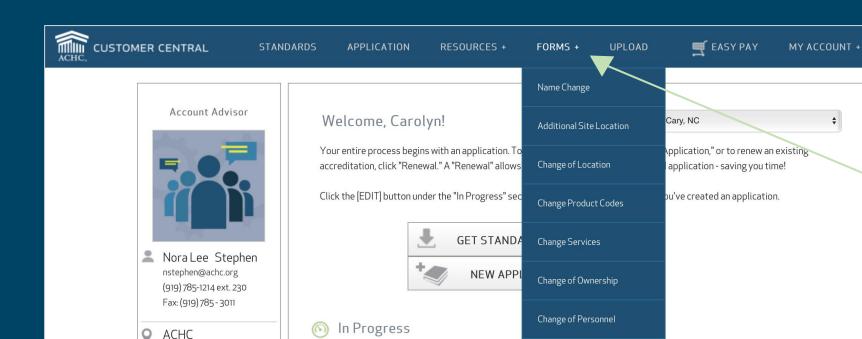




Customer Central Regulatory Resources







APPLICATION

103738

COMPANY

Accreditation History

DATE SUBMITTED

DATE SUBMITTED

Closure/Withdrawal

PAYMENT

Customer In Progress

Notification

LAST UPDATED

4/26/2019 8:06 AM

ACCREDITATION DATE

[EDIT]

STATUS

Use the FORMS tab to edit company information



139 Weston Oaks Ct.

Customer Central Tour Application Tour

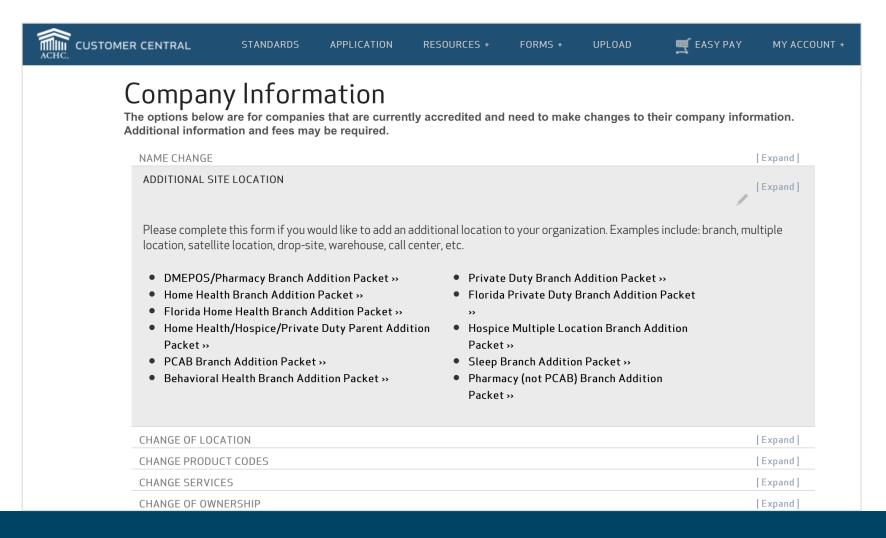
Cary, NC 27513

Video Tutorials

PER "How To" On-Site Survey POC "How To"



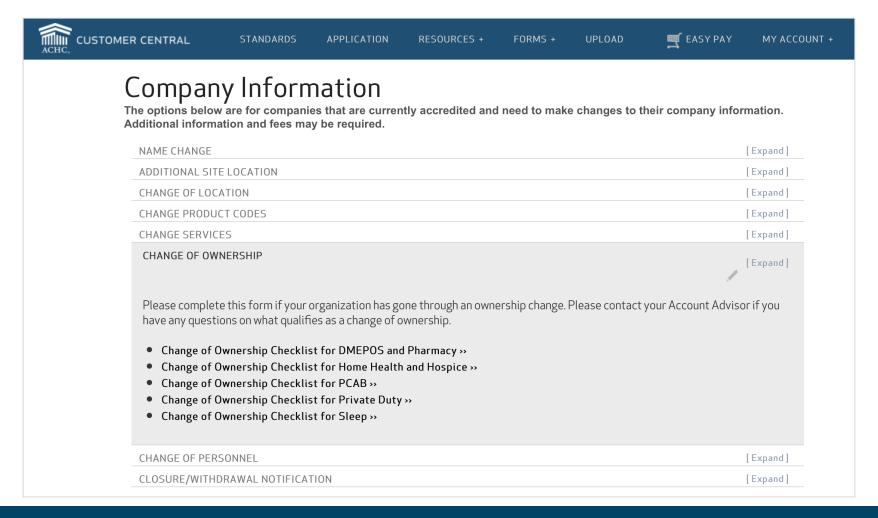
Branch Addition





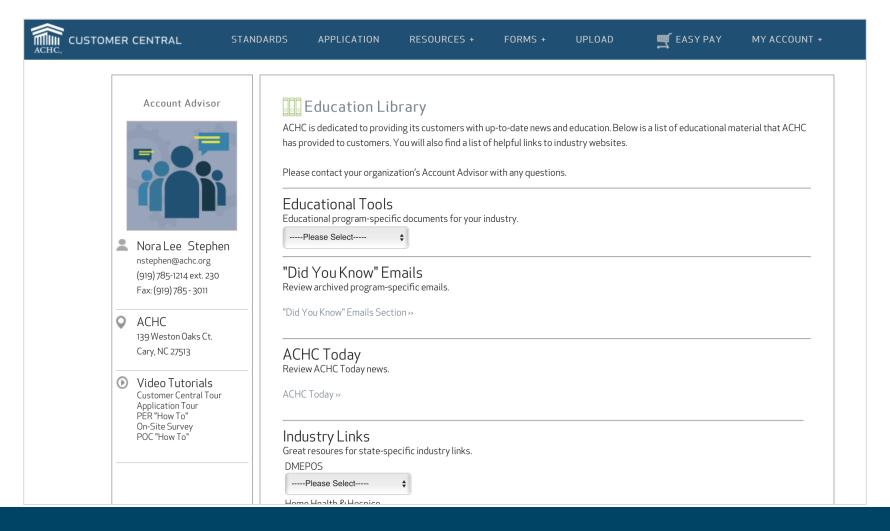


Change of Ownership





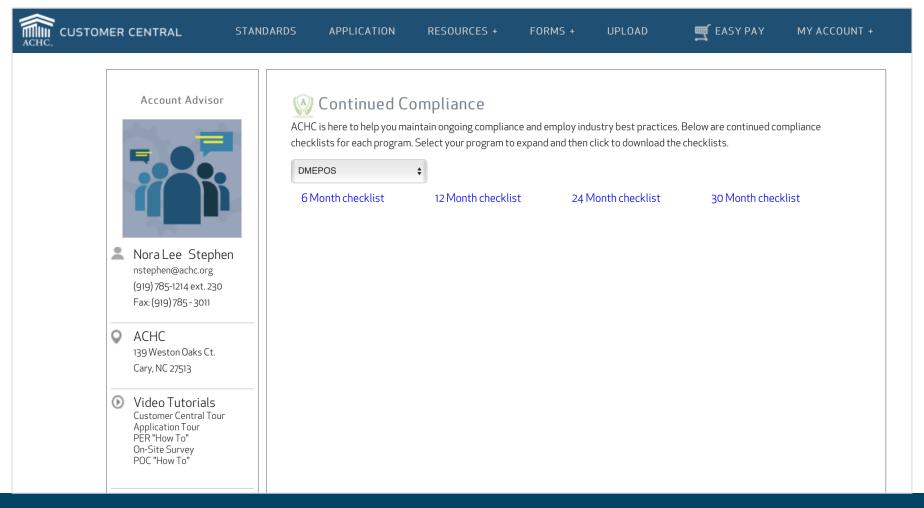
Education Library





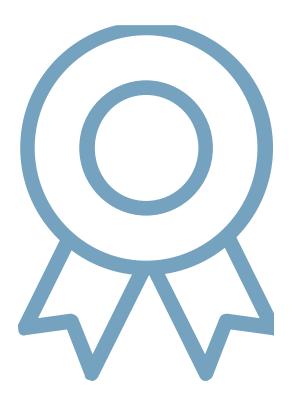


Continued Compliance





Congratulations!





Account Advisors

- Key resource in navigating the accreditation process
- Experts on the process, but not Pharmacists
- If asking a regulatory or pharmacy practice question, your Account Advisor will direct your question to the appropriate clinical or regulatory department
- Phone calls are good, but a well-worded email can help get you the most accurate answers
- Customer Central and your workbook can answer many of the most common process questions



Survey Day/Surveyor

- Who is your Surveyor?
 - Registered Pharmacist
 - Expert on the process of sterile and non-sterile compounding
 - 20-plus years of experience
 - United States Pharmacopeial Convention (USP) experience and knowledge
 - Completed comprehensive ACHC/PCAB training
 - Completed required field training (precept)
 - Background checks and completed Business Associate Agreement (BAA)
 - Selected for your survey based on experience
 - Asked to verify that survey does not create conflict of interest
 - You will not know the name of your Surveyor in advance



Survey Day

- The Surveyor is only a data collector; the Surveyor does not play any role in the ultimate review decision or the accreditation status (don't get mad at him/her)
- The Surveyor will have an identification badge
- The Surveyor will not leave a business card
- All post-survey communication will be through your Account Advisor
- The Surveyor cannot accept an invitation to dinner
 - Lunch is acceptable, if provided to the entire office
- Management is invited to be involved in all aspects of the survey



Survey Day

- Try to keep your staff relaxed and focused
- Patients come first (just keep us in the loop)!
- Perfection is not the goal of the day
- Almost everything can be "fixed"
- You are encouraged to fix "simple" things during survey
- There is nothing your staff can say in an interview that will sink the ship
- Deficiencies are common...and expected
- Don't get sidetracked by "what's my score?"
- Ask questions/clarification
 - The Surveyor is not always correct, so challenge him/her
 - The Surveyor will discuss all noted deficiencies at closing seek clarification



Post-Survey Process

 Summary of Findings (SOF) — An SOF will be sent to the organization within 10 business days following the last day of the survey; the SOF is the final account of deficiencies and will be the basis for the Plan of Correction (POC)

(Sample on next slide.)



p. 25

Sample SOF

Survey Report for Survey on





Deficiency Category - Interviews/Observations Standard

Comments

Deficient

TCRX5-G Written policies and procedures are established and implemented regarding continuous quality control for finished preparations.

testing to competency assessment of staff. They are in the process of performing some potency over time testing to extend BUDs of the topical preparations; however, this has not been identified as a staff competency assessment.

The pharmacy has not related the results of potency

Action Required: The pharmacy needs to develop a process for using the potency testing to assess competency.

The pharmacy's plan may include the following: Potency testing of finished preparations: Each compounder's finished preparation is tested for potency in each of the following dosage forms they prepare: capsules, suppositories, creams/ointments every six months.

The pharmacy needs to revise the P&P that governs competency assessments to include using the potency tests. The pharmacy needs to train pertinent staff and then verify ongoing compliance by auditing the personnel files to verify that the tests have been performed and that they have acceptable results. The results of the audit need to be stored in the PI binder.



Deficiency Category - Pharmacy with Evidence Required on POC Standard Comments

Deficient



Written policies and procedures are established and implemented requiring all non-sterile compounding personnel to receive training and/or education and to competently perform the required client/patient service activities prior to being assigned to work independently. The pharmacy provided evidence of a recently developed annual competency assessment for staff. The competency assessment was an observational audit that was performed during the compounding of a topical preparation. The assessment did not include a potency test. The assessment was for only one type of dosage form and the pharmacy also prepares suppositories and capsules.

Initial competency assessments, at the time of hire and before compounding, were performed and not documented.

It is noted that the pharmacy provided evidence of a read and understand document for each of the P&Ps. It was discussed during the survey, that the read and understand is not a documented competency assessment; however, the P&P could be used as an audit tool for future competency assessments along with the compounding record and potency test.

Action Required: The pharmacy's plan of correction needs needs to include developing an audit tool that





Accreditation Decision Definitions



ACCREDITED

Provider meets all requirements for full accreditation status.

Accreditation is granted but Plan of Correction (POC) may still be required.*



ACCREDITATION PENDING

Provider meets basic accreditation requirements but accredited status is granted upon submission of an approved POC.



DEPENDENT

Provider has significant deficiencies to achieve accreditation. An additional on-site visit will be necessary to be eligible for accreditation.



DENIED

Accreditation is denied. Provider must start process from the beginning once deficiencies are addressed.



Post-Survey Process

- Plan of Correction (POC) The POC template will be sent electronically from your Account Advisor
 - All documentation must be on the POC template
 - Allows you to document the plan to correct each deficiency noted on the SOF as well as your plan to prevent a recurrence
 - POC must be submitted electronically



PLAN OF CORRECTION (POC)



ONCE COMPLETED, PLEASE EMAIL THIS FORM TO THE ATTENTION OF YOUR ACCOUNT ADVISOR

Organization: Greg's Pharmacy

Standard	Plan of Correction (Specific action taken to bring standard into compliance)	Date of Compliance (Date correction to be completed)	Title (Individual responsible for correction)	Process to Prevent Recurrence (Describe monitoring of corrective actions to ensure they effectively prevent recurrence)	POC Compliant (ACHC internal use only)	Comments (ACHC internal use only)
TCRX3-B	What would be a proper POC for this deficiency?	What's a reasonable time frame?		How do you prevent this from happening again?		





Plan of Correction (POC)

- Required when a deficiency is found
- Must be submitted within 30 days from receipt of an accreditation decision letter and necessary supporting documentation, if applicable
- Follow a specific format
- Submitting a thorough and complete POC will expedite your accreditation
- All deficiencies require a POC
- Some deficiencies require evidence of correction



Example: Non-compliance

Standard TCRX3-B: Written policies and procedures are established and implemented requiring all sterile compounding personnel to receive training and/or education and to competently perform the required client/patient service activities prior to being assigned to work independently.

- Surveyor Observation:
 - "Three of five sterile compounding staff (JU, JS, MG), documented results for only one hand of gloved fingertip sample."
- Action Requirement
 - "All sterile compounding staff are required to complete gloved fingertip samples of both hands every six months. "



Sample Plan of Correction





DNCE COMPLETED, PLEASE EMAIL THIS FORM TO THE ATTENTION OF YOUR ACCREDITATION ADVISOR

Organization:

Greg's Pharmacy

ACHC INTERNAL USE ONLY

Standard (Insert standard #)	Plan of Correction (Specific action taken to bring standard into compliance)	Date of Compliance (Date correction to be completed)	Title (Individual Responsible for Correction)	Process to Prevent Recurrence (Describe monitoring of corrective actions to ensure they effectively prevent recurrence)	Compliant (Yes/No)	Comments
TCRX3-B	What would be a proper POC for this deficiency?	Whats a reasonable time-frame?		How do you prevent∣this from happening again?		





Key Preparation Tips

- Strategies for a successful survey
- A look at common deficiencies and survey pitfalls





Preparing Your Organization

- Performing your own survey
- Interview staff
- Review records
- Trace a finished preparation backwards



Common Problem Areas

- Personnel
 - Orientation
 - Training
 - Competency
- Facilities
 - Cleanroom
 - Cleaning and disinfection
 - Environmental monitoring



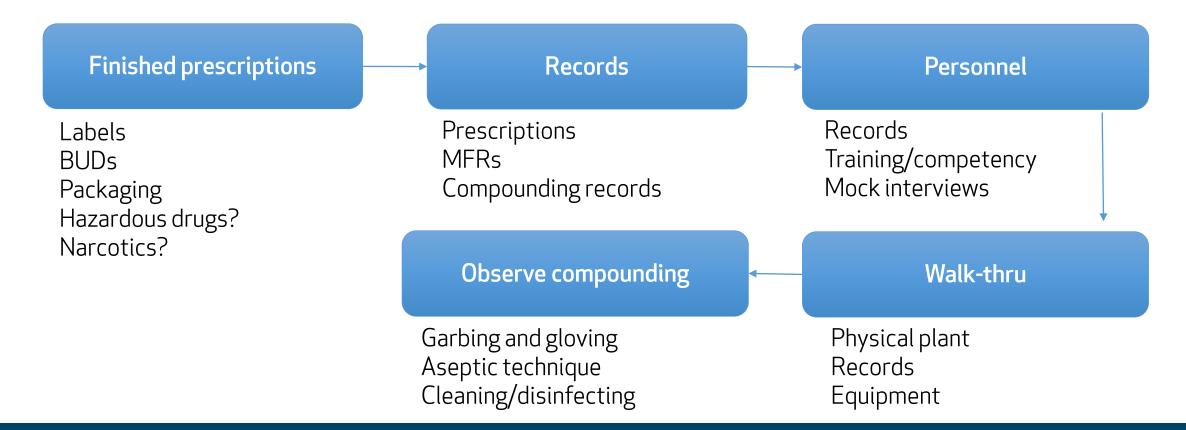
Common Problem Areas

- Compounding practices
 - Cleanroom technique/etiquette
- Beyond-Use Dates (BUDs)
- Sterility and endotoxin
- Equipment
 - Pharmacy equipment
 - Administration equipment
- Documentation



Tip: Survey Yourself!

Work backwards









THANK YOU

Accreditation Commission for Health Care 139 Weston Oaks Ct., Cary, NC 27513 (855) 937-2242



