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PCAB PHARMACY WORKSHOP

MAY 2018

ACHC

PCAB PHARMACY COMPOUNDING ACCREDITATION BOARD

AccreditationUniversity.com

ACCREDITATION COMMISSION *for* HEALTH CARE

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PHARMACY

ACHIEVING PCAB ACCREDITATION

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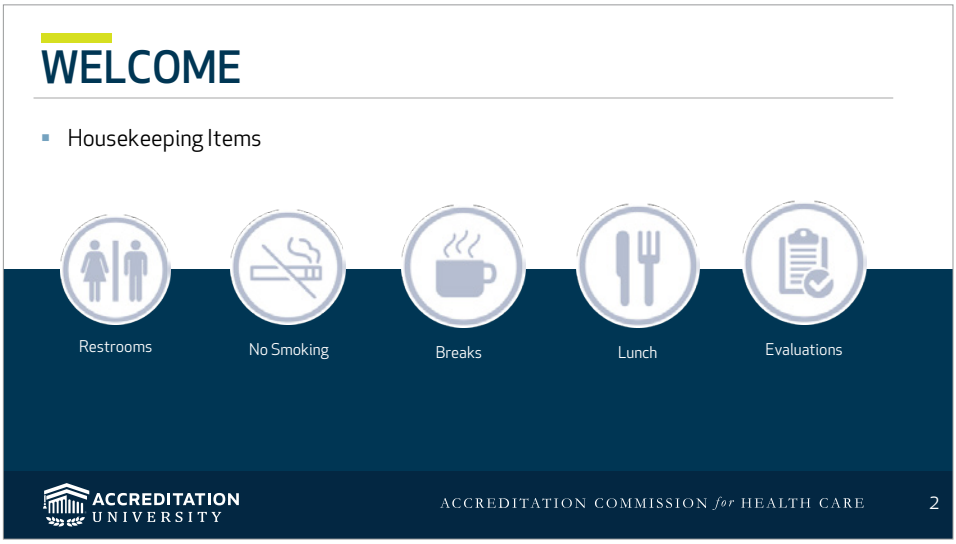
ACHIEVING PCAB ACCREDITATION



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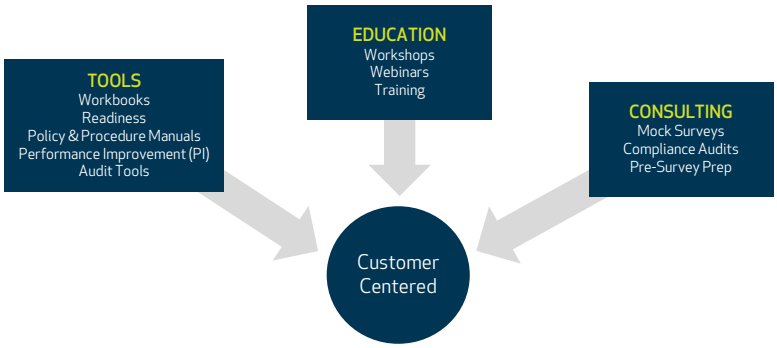

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- Accreditation University (AU) is dedicated to your organization's success
- Learn more about AU at AccreditationUniversity.com or talk with a representative today

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PHARMACY

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PHARMACY

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PHARMACY

JOSÉ DOMINGOS

President & CEO

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INTRODUCTIONS

- Name
- Company name and your title
- Where is your company located?
- What does your pharmacy do?
- How many years in the industry?
- New to PCAB or a renewal?

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LEARNING OBJECTIVES (DAY 1)

- Understand PCAB requirements for non-sterile and sterile compounding
- Learn the key differences between revised PCAB standards and legacy PCAB standards
- Become familiar with the initial and renewal accreditation process
- Detail the essential components of a functional Performance Improvement (PI) Program
- Learn how to prepare an organization for the PCAB Accreditation survey
- Establish expectations for survey day and strategies for survey success
- Get a detailed look at the post-survey process (Plan of Correction [POC])
- Review the "common" standards deficiencies
- Learn how to utilize the *ACHC Accreditation Guide to Success* workbook to ensure ongoing compliance

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WORKSHOP AGENDA

- In your handout
- This morning is all about the process of PCAB Accreditation
- Balance of the day - PCAB standards
- Work groups
- Day 2 – Detailed look at USP <800>
- Agenda is a guide; you drive the depth of each topic
- Questions are encouraged
- Use breaks to ask specific questions and get clarification
- Get to know your classmates (great resource)
- Room temperature, breaks, restrooms, and additional resources
- Wrap up for travel tomorrow?

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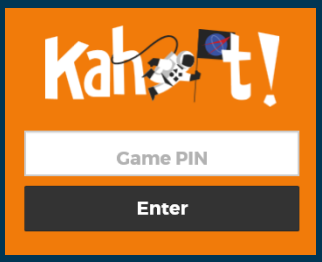
TEACHING TOOL: Kahoot!

- Cell phone or laptop
- Go to Kahoot.it
- Enter Game PIN
- Enter your Nickname (Use your initials + zip code, e.g. CR27513)
- See "You're in"
- You're Ready!



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PCAB AND ACHC

- PCAB Accreditation became a service of ACHC in July 2014

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PCAB ACCREDITATION

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

Pharmacy Services:
AIC – Ambulatory Infusion Center
IRN– Infusion Nursing
IRX– Infusion Pharmacy
SRX– Specialty Pharmacy
SRX Only – SRX without DMEPOS
LTC - Long Term Care Pharmacy
PCAB Accreditation
CFNS – Non-Sterile Compounding (Ref. USP <795>)
CFST – Sterile Compounding (Ref. USP <797>)
AIS - ACHC Inspection Services
Distinctions*
ONC – Distinction in Oncology
HDH – Distinction in Hazardous Drug Handling
HIV– Distinction in Infectious Disease Specific to HIV
NTS – Distinction in Nutrition Support

*The provider must be accredited with ACHC to be eligible for a distinction service.

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DISTINCTION IN HAZARDOUS DRUG HANDLING

PHARMACY COMPOUNDING ACCREDITATION BOARD ACCREDITED

DISTINCTION IN HDH

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ACHC PROGRAMS & SERVICES

HOME HEALTH
Home Health Aide
Medical Social Services
Occupational Therapy
Physical Therapy
Skilled Nursing
Speech Therapy

HOSPICE
Hospice Inpatient Care
Hospice Care

PRIVATE DUTY
Private Duty Aide
Private Duty Companion/Homemaker
Private Duty Infusion Nursing
Private Duty Nursing
Private Duty Occupational Therapy
Private Duty Physical Therapy
Private Duty Speech Therapy
Private Duty Social Work

DMEPOS
Community Retail
Clinical Respiratory Care Services
Fitter
Home/Durable Medical Equipment
Medical Supply Provider
Complex Rehabilitation and Assistive Technology Supplier

SLEEP
Sleep Lab/Center
Home Sleep Testing

AMBULATORY CARE
Convenient Care Clinics

BEHAVIORAL HEALTH
ACHC offers a variety of Behavioral Health services to suit your accreditation needs. Contact ACHC for details or visit achc.org for a complete listing of services available.

PHARMACY
Ambulatory Infusion Center
Infusion Nursing
Infusion Pharmacy
Specialty Pharmacy
> SRX without DMEPOS
Long Term Care Pharmacy
PCAB Accreditation (A Service of ACHC)
> Non-Sterile Compounding (Ref. USP <795>)
> Sterile Compounding (Ref. USP <797>)
ACHC Inspection Services (AIS)

DISTINCTIONS*
Distinction in Behavioral Health
Distinction in Hazardous Drug Handling
Distinction in Infectious Disease Specific to HIV
Distinction in Nutrition Support
Distinction in Oncology
Distinction in Palliative Care

*The provider must be accredited with ACHC to be eligible for a distinction service.

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PHARMACY ACCREDITATION

All ACHC Pharmacy Accreditation programs are based on patient-specific 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

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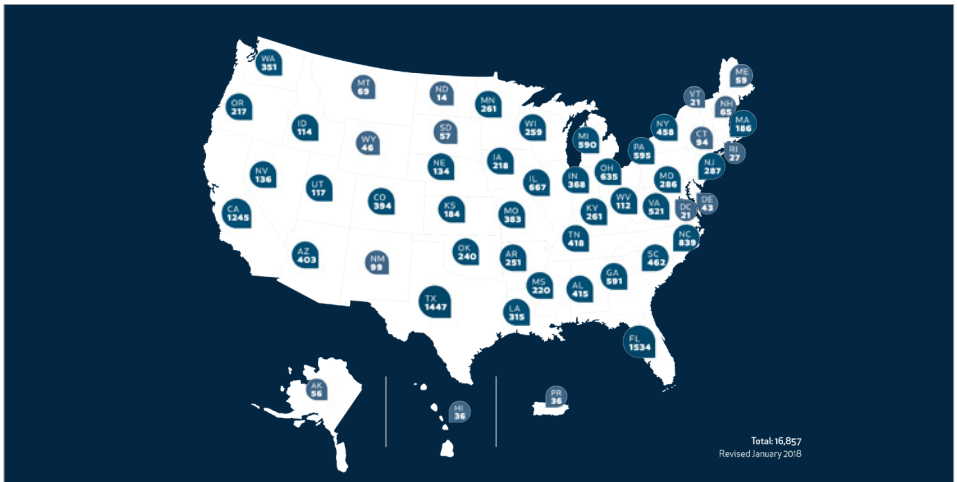

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ACHC MISSION & VALUES

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

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TODAY'S LEARNING GUIDE

ACHC Accreditation Guide to Success workbook for Compounding Pharmacy

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HOW TO USE THE WORKBOOK

- Page 1.1 Look at Section 1
  - Note shaded areas
  - Surveyor "Hints"
- Pages 13-15 Quick Standard Reference
- Pages 17-26 Survey Process
- Pages 31-33 Global Staff Interview Questions
- Pages 35-37 Practice Run Audit Tool

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HOW TO USE THE WORKBOOK

"30,000 ft. overview"

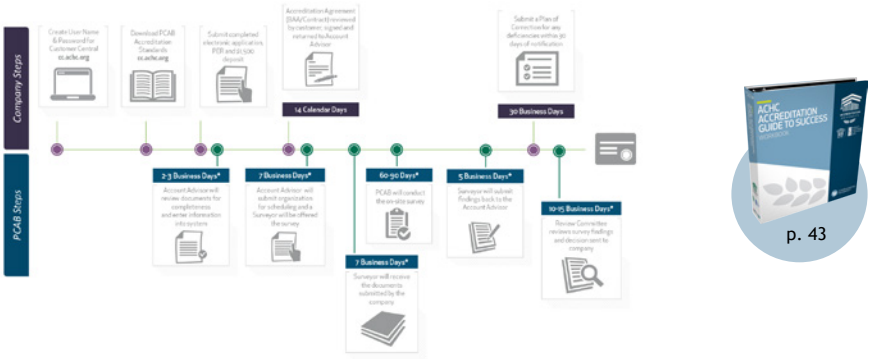
- Page 3.6 Tools Available
- Page 3.9 Compliance Checklist
- Page 3.12 Sample Documents
- Page 3.14 Staff Training Audit Tool
- Page 3.16 Ongoing Assessments
- Page 3.20 Compounding Competencies
- Page 3.24 Process Analysis

HOW TO USE THE WORKBOOK

- Pages 4.5 – 4.9 Client Record Audit Tools
- Pages 5.11 – 5.28 Performance Improvement Tools
- Pages 6.18 – 6.56 Compounding Process
- Pages 7.6 – 7.35 Continued Compliance

ACHIEVING PCAB ACCREDITATION

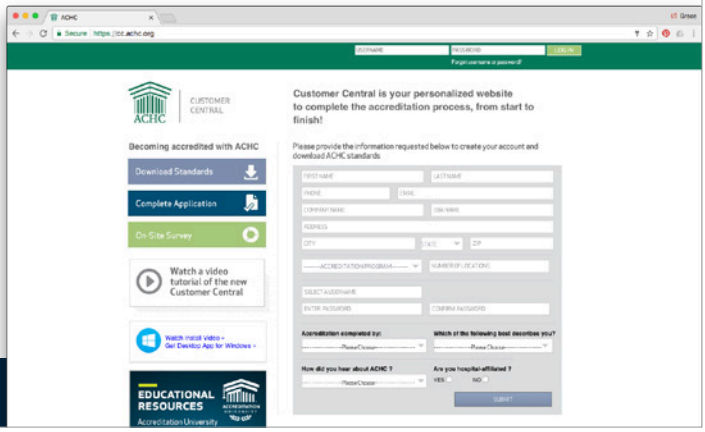
ACCREDITATION PROCESS



STEP 1: REGISTRATION

ACHC CUSTOMER CENTRAL

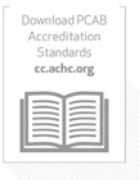
- Customer Central: cc.achc.org

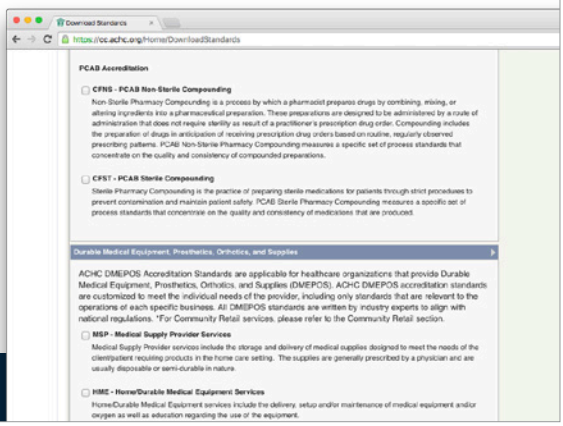


STEP 2: STANDARDS

ACHC CUSTOMER CENTRAL

- 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





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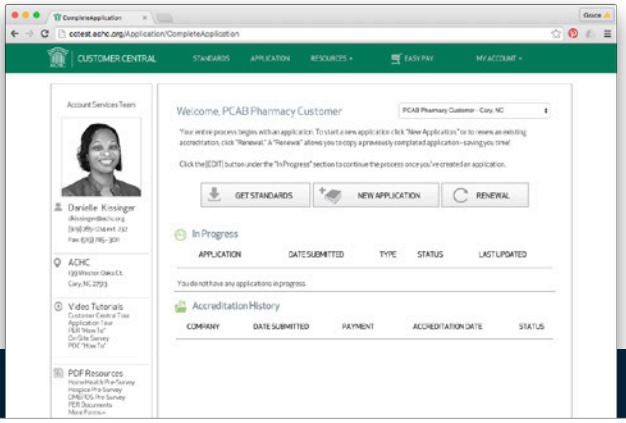
STEP 3: APPLICATION

CUSTOMER CENTRAL

Submit completed electronic application, PER and $1,500 deposit



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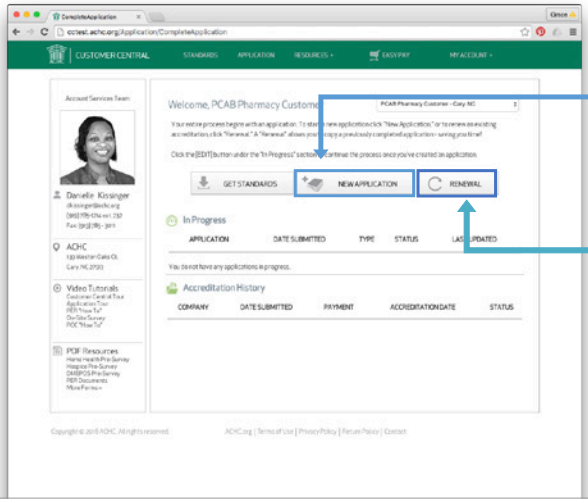

- If this is your first time with ACHC accreditation, click the "NEW APPLICATION" button.
- If you're in an existing accredited account (PCAB or ACHC), you can click on the "RENEWAL" button to save time.

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STEP 3: APPLICATION

CUSTOMER CENTRAL

2-3 Business Days*

Account Advisor will review documents for completeness and enter information into system

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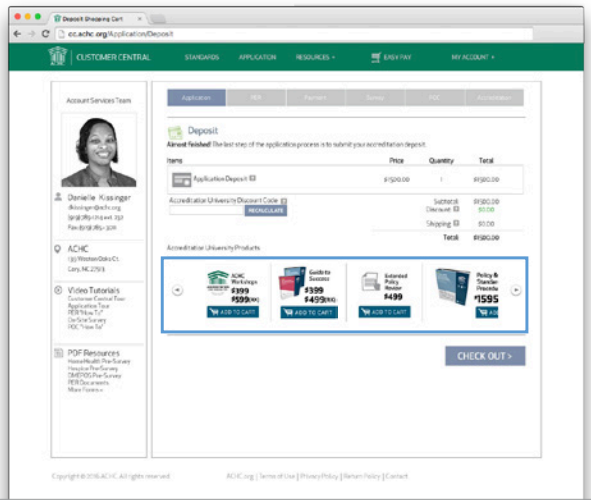

When the application is submitted, you will be prompted to complete the deposit payment.

ACHC accepts both credit cards and checks.

Additional Resources are available for your client below.

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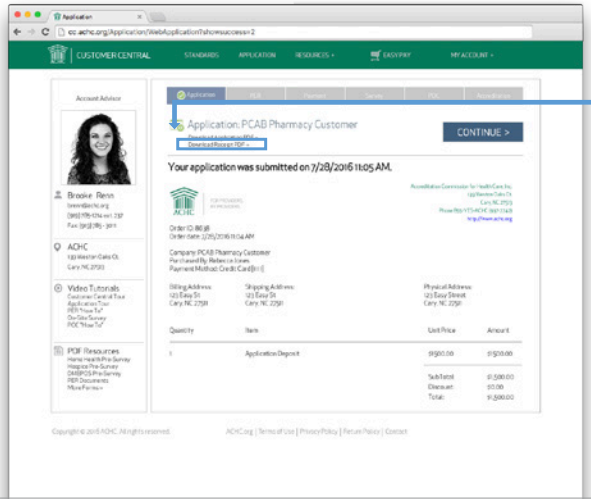

Each transaction will display a receipt. Click "Download Receipt PDF" save a PDF copy.

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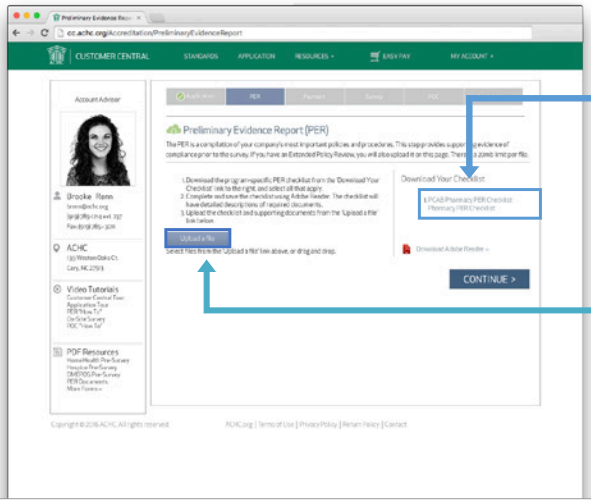

- First, download the correct PER checklist.
- Completely fill out the PER checklist and upload with supporting documents.

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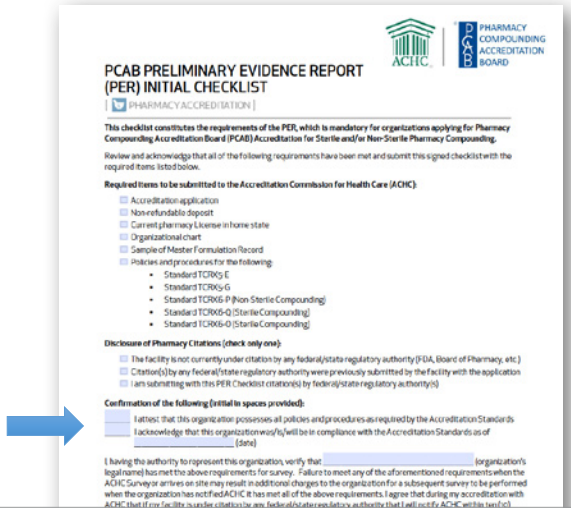

PCAB PRELIMINARY EVIDENCE REPORT (PER) INITIAL CHECKLIST

PHARMACY ACCREDITATION

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.

Required items to be submitted to the Accreditation Commission for Health Care (ACHC):

- 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)

I having the authority to represent this organization, verify that _____ (organization's legal name) has met the above requirements for survey. Failure to meet any of the aforementioned requirements when the ACHC Survey or arrives on site may result in additional charges to the organization for a subsequent survey to be performed when the organization has notified ACHC it has met all of the above requirements. I agree that during my accreditation with ACHC that if my facility is under citation by any federal/state regulatory authority that I will notify ACHC within ten (10)

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STEP 4: AGREEMENT

CUSTOMER CENTRAL

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

14 Calendar Days

Payment Information

Deposit Received:
<<<INSERT DEPOSIT AMOUNT HERE>>>

Discount (if applicable):
<<<INSERT DISCOUNT AMOUNT HERE>>>

Remaining Balance: <<<REMAINING BALANCE>>>

<<<FIRST PAYMENT>>> Due on line upon execution of this Agreement.

<<<SECOND PAYMENT>>> Due 12 months from date of the Accreditation Decision Letter.

<<<THIRD PAYMENT>>> Due 24 months from date of the Accreditation Decision Letter.

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

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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?
  - New application: Some point after "Date of Readiness" (excluding Blackout dates)
  - Renewal: Based on when you apply, and when accreditation expires

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ACHIEVING PCAB ACCREDITATION

SURVEY

ACHC | CUSTOMER CENTRAL

7 Business Days*

Account Advisor will submit organization for scheduling and a Surveyor will be offered the survey

SURVEY

ACHC | CUSTOMER CENTRAL

7 Business Days*

Surveyor will receive the documents submitted by the company

SURVEY

ACHC | CUSTOMER CENTRAL

60-90 Days*

PCAB will conduct the on-site survey

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SURVEY

ACHC CUSTOMER CENTRAL

5 Business Days*

Surveyor will submit findings back to the Account Advisor

ACCREDITATION DECISION

ACHC CUSTOMER CENTRAL

10-15 Business Days*

Review Committee reviews survey findings and decision sent to company

ACHC 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.

ACHIEVING PCAB ACCREDITATION

POST-SURVEY PROCESS

ACHC | CUSTOMER CENTRAL

- 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)

(We will cover in more detail later)

PLAN OF CORRECTION

ACHC | CUSTOMER CENTRAL

CONGRATULATIONS!

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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+ 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

ACHIEVING PCAB ACCREDITATION

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

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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)

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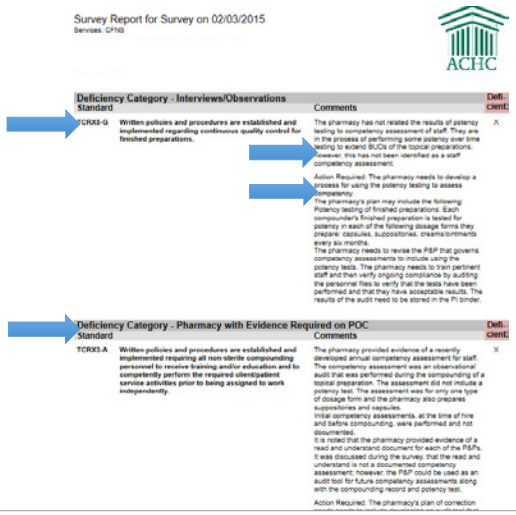
SAMPLE SOF


Survey Report for Survey on 02/03/2015

Services: CPNS

ACHC

Deficiency Category - Interviews/Observations			
Standard		Comments	Defi-cient:
TCRX8-G	Written policies and procedures are established and implemented regarding continuous quality control for finished preparations.	The pharmacy has not related the results of potency 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. 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.	X

Deficiency Category - Pharmacy with Evidence Required on POC			
Standard		Comments	Defi-cient:
TCRX1-A	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	X

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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

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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)
TCR3-B	What would be a proper POC for this deficiency?	What's a reasonable time frame?		How do you prevent this from happening again?		

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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

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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:*
  - "3 of 5 sterile compounding staff, (JU, JS, MG), documented results for only 1 hand of gloved fingertip sample."
- *Action Requirement*
  - "All high-risk sterile compounding staff are required to complete gloved fingertip samples of both hands every 6 months."

SAMPLE PLAN OF CORRECTION

PLAN OF CORRECTION (POC)

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

ACHC FOR PROVIDERS. BY PROVIDERS.®

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

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PREPARING YOUR ORGANIZATION

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

COMMON PROBLEM AREAS

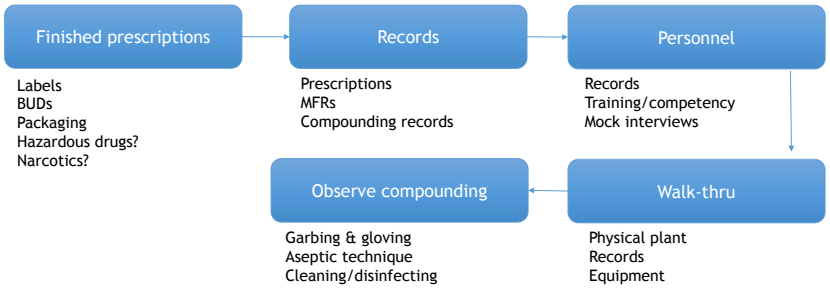
- Personnel
  - Orientation (Checklist page 3.12)
  - Training (Checklist page 3.16)
  - Competency (Checklist page 3.20)
- Facilities
  - Cleanroom (page 6.38)
  - Cleaning and disinfection
  - Environmental monitoring

COMMON PROBLEM AREAS

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

TIP: SURVEY YOURSELF!

- Work backwards



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Section 6

STANDARD TCRX6-A

Standard TCRX6-A: Written policies and procedures are established and implemented that address the surveillance, identification, prevention, control and investigation of infectious and communicable diseases and the compliance with regulatory standards.

Interpretation: The organization maintains and documents an effective infection control program that protects clients/patients and personnel by preventing and controlling infections and communicable diseases. The organization's infection control program must identify risks for the acquisition and transmission of infectious agents. There is a system to communicate with all personnel about infection prevention and control issues including their role in preventing the spread of infections and communicable diseases through daily activities.

Written policies and procedures are established and implemented to include accepted standards of practice to prevent the transmission of infections and communicable diseases, including the use of standard precautions.

Section 6

STANDARD TCRX6-A (CONTINUED)

Accepted standards of practice for health care providers are typically developed by government agencies, professional organizations and associations.

Written policies and procedures include, but are not limited to:

- General infection control measures appropriate for service provided
- Hand washing
- Use of standard precautions and personal protective equipment (PPE)
- Needle-stick prevention and sharps safety, if applicable
- Appropriate cleaning/disinfecting procedures
- Infection surveillance, monitoring, and reporting of employees and clients/patients
- Disposal and transportation of regulated waste, if applicable

Section 6

STANDARD TCRX6-A (CONTINUED)

- Employee health conditions limiting their activities
- Assessment and utilization of data obtained about infections and the infection control program
- If the pharmacy compounding activities require the manipulation of a patient's blood-derived or other biological material, the pharmacy is compliant with the OSHA Bloodborne Pathogens Standard

Written policies and procedures identify the personnel who are responsible for implementing the infection control activities and personnel education.

Section 6

STANDARD TCRX6-B

Standard TCRX6-B: Written policies and procedures are established and implemented for preparation and/or component recall.

Interpretation: The pharmacy has a mechanism for identifying, in a timely and effective manner, which clients/patients received recalled compounded preparations or their components.

External recalls –when a vendor recalls an active pharmaceutical ingredient (API) or excipient
- APIs- who got this ingredient?
- Excipients- who got this excipient or diluent?

Internal recalls – when a preparation does not meet quality or safety requirements.
- Batches- who got this batch?
- Prescriptions-who got this prescription?
- How are patients and prescribers notified?
- Is the recall documented properly?

Preparation:
Test your recall system … **Your Surveyor will!**

Section 6

STANDARD TCRX6-C

Standard TCRX6-C: Written policies and procedures are established and implemented relating to the storage of pharmaceuticals, components (including active pharmaceutical ingredients, excipients, ingredients, and devices) and compounded preparations.

- Hazardous drugs should have their own section
- Acids and bases low down, secondary containment away from each other

Problem areas
- What is wrong with this refrigerator temperature log?
- What information should labels of stock bottles filled from bulk containers have?
- How are stock bottles cleaned and disinfected?
- How are the contents of stock bottles verified?

M	T	W	Th	F	S	Su
35 F	34 F	33 F	32 F	32 F	31 F	33 F

Section 6

STANDARD TCRX6-D

Standard TCRX6-D: The organization uses delivery containers that ensure pharmaceuticals are maintained under appropriate conditions of sanitation, light and temperature in the course of deliveries.

- Proper containers – coolers/icepacks are available and used appropriately and consistently
  - Tip: Specialty pharmacies have SOPs for the size of the package, number of ice bricks, etc.
- Personnel receive training in packing and shipping
- Final check before sealing
- Must verify that your containers maintain appropriate storage conditions
  - Include an indicator in all packages that require temperature control and include instructions to the patient as to what to do if the indicator shows an out of range temperature; or

NOTES

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Section 6

STANDARD TCRX6-D (CONTINUED)

- Test packaging under various weather conditions, such as summer, winter, etc., by including an indicator in a sample of X packages and verifying the results with patients

FYI – Georgia requires an indicator in every package, so check state laws!

Section 6

STANDARD TCRX6-E

Standard TCRX6-E: Written policies and procedures are established and implemented by the Pharmacy relating to the appropriate use, calibration, cleaning and as appropriate, disinfection or sterilization of equipment used for preparing, dispensing, labeling, and shipping of preparations.

- This standard covers a broad area in both sterile and non-sterile compounding!
- Calibration are performed and logged
  - Balances – daily or when used
  - Level the balance
  - pH meters – when used or per manufacturer's instructions
  - Thermometers

Section 6

STANDARD TCRX6-E (CONTINUED)

Standard TCRX6-E: Written policies and procedures are established and implemented by the Pharmacy relating to the appropriate use, calibration, cleaning and as appropriate, disinfection or sterilization of equipment used for preparing, dispensing, labeling, and shipping of preparations.

- Personnel know how to use the equipment
  - Hint: Minimum weighable quantity is often a problem
- Cleaning and disinfection
  - All equipment and utensils as appropriate
  - A compounding record can be used to document this
- Equipment must be appropriate for its use
  - Balances must be laboratory grade devices
  - Convection oven must "convect"

← Bad idea!

CLEANROOM EQUIPMENT

Use appropriate equipment!

- Suitable for intended use
- Properly calibrated
  - NIST calibration
    - Thermometers
    - Weights
- Properly verified
  - Biological indicators
  - Endotoxin challenge vials

California State Board of Pharmacy
March 21, 2014

Section 6

STANDARD TCRX6-F

Standard TCRX6-F: Written policies and procedures are established and implemented for compounding preparations that outline the selection of ingredients and are in compliance with applicable law, regulations and standards of good practice.

Key points:

- Use Food and Drug Administration (FDA)-registered suppliers
- Establish criteria for acceptance
- Use the Certificate of Analysis (COA) data as appropriate to incorporate into Master Formulation Records (MFRs)
  - Water content
  - Potency
- FDA negative list – hint: Adenosine Phosphate a.k.a. Monophosphate

Section 6

STANDARD TCRX6-F (CONTINUED)

- Approved drug in the U.S, or USP/National Formulary (NF) Monograph
  - FDA still working on "difficult" list
- If no expiration – one year from receipt (ST) or three years (NS)

NOTES

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Section 6

STANDARD TCRX6-G

Standard TCRX6-G: Written policies and procedures are established and implemented that outline the contents of the Master Formulation Record for each compounded preparation.

Interpretation: Written policies and procedures are established and implemented in regard to the use of a formulation record that provides the pharmacy with a consistent source document for preparing each compounded preparation. The process is consistent with applicable laws and regulations.

There is an MFR for each preparation that includes

- Name, strength and dosage form
  - Ingredients and their quantities
  - Pertinent calculations
- Equipment and equipment settings used to produce the preparation

Section 6

STANDARD TCRX6-G (CONTINUED)

- Mixing and/or other pertinent instructions
- Quality control procedures and expected results
- Compatibility and stability information including references when available
- Beyond-Use Date (BUD)
- Container and packaging used for dispensing
- Packaging and storage requirements
- Labeling information including generic name and quantity/concentration of each active ingredient
  - pH
  - Sterility testing
  - Endotoxin testing
  - Potency testing

Section 6

STANDARD TCRX6-H

Standard TCRX6-H: Written policies and procedures are established and implemented that outline the contents of the compounding record for each preparation.

Interpretation: Written policies and procedures are established and implemented in regard to the use of a compounding record that documents the actual ingredients in a preparation, the person responsible for compounding, and the Pharmacist who approves the finished preparation. The process is consistent with applicable laws and regulations.

CFST Only: When regulations permit an exemption to the above requirements, the pharmacy has a compounding record that contains the correct identities, purities, and amounts of ingredients in the preparation.

Section 6

STANDARD TCRX6-H (CONTINUED)

There is a compounding record for each preparation that includes:

- Formulation record used
- Ingredients and quantity of each, lot, expiration date, manufacturer or source
- Quantity prepared
- Names of the individual(s) making the preparation
- Signature or initials of the supervising Pharmacist responsible for in-process and final checks
- Date of preparation
- Prescription or batch number
- Assigned BUD
- Results of quality control procedures (weight, adequacy of mixing, clarity, odor, color, consistency, pH, and analytical testing, as appropriate to each dosage form)

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HINT

- Incomplete records are a problem for many organizations
  - Compounding records missing key elements – expiration dates, lots, etc.
  - Quality control data – pH, filter integrity test (ST), etc.
  - Recorded lots don't match the actual ingredient
- You now know how to avoid it!

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Section 6

STANDARD TCRX6-I

Standard TCRX6-I: Written policies and procedures are established and implemented in regard to compounding non-sterile preparations in accordance with USP Chapter <795> standards, the art and science of pharmacy, applicable laws and regulations.

Interpretation: Personnel use appropriate techniques to compound preparations. Written policies and procedures are established and implemented to ensure preparations are made in accordance with applicable USP standards, the art and science of pharmacy, and applicable laws and regulations.

Written policies and procedures define how compounding is performed, including but not limited to:

- How critical processes are performed (including but not limited to weighing, measuring, and mixing)

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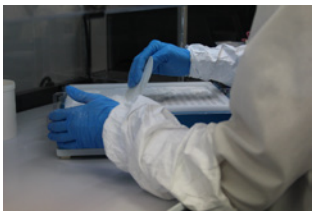
Section 6

STANDARD TCRX6-I (CONTINUED)

- How dosage forms are prepared according to applicable USP standards, the art and science of pharmacy, and applicable laws and regulations
- Checks and rechecks for each procedure at each stage of the process
- Compounding preparations using the MFR, the compounding record, and associated written procedures, documenting any deviation in procedures

ASSESSMENT OF NON-STERILE COMPOUNDING

- Observation
  - Surveyor chooses
  - Any staff member may be selected



- Interview
  - How were you trained?
  - How do you…?
  - What do you consider hazardous?
  - What if you had a spill?
  - Where is your eye wash?
- Documentation Review
  - Does it match observation?
  - Is it complete and accurate?
  - Is it appropriate?

Section 6

STANDARD TCRX6-J

Standard TCRX6-J: Written policies and procedures are established and implemented in regard to hazardous non-sterile compounded preparations are compounded in an environment that meets requirements as defined by USP Chapter <795>, state boards of pharmacy regulations, and standards of good practice.

Interpretation: Written policies and procedures define appropriate garb and personal protective equipment (PPE) (e.g. gowns, face masks, eye protection, hair covers, shoe covers, and double gloving with chemotherapy gloves) to compound hazardous preparations per the current The National Institute for Occupational Safety and Health (NIOSH) list of Antineoplastic and other Hazardous Drugs in Healthcare Settings.

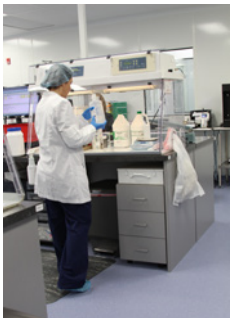
Section 6

STANDARD TCRX6-J (CONTINUED)

Interpretation: The pharmacy has the proper environment to prepare non-sterile hazardous preparations which, at a minimum, include performing manipulations within a Class I biological safety cabinet (BSC). The Class I BSC environment(s) are maintained and certified per the manufacturer's requirements. A qualified independent contractor performs annual certification according to accepted standards for operational efficiency. The work surface of the BSC is decontaminated after compounding with hazardous drugs.

CLASS I BSCS TIPS AKA "POWDER HOODS"

- Certified (Occupational Safety and Health
- Administration [OSHA], Manufacturer's requirements)
- Used to
  - Protect from hazardous drugs
  - Prevent cross-contamination
  - Protect from irritants and potent drugs
- What is hazardous?
  - National Institute for Occupational Safety and Health (NIOSH) List
    - Hormones
    - DES
    - HCG
    - Antineoplastics
  - Not limited to NIOSH list – OSHA requires evaluation:
    - Cantharidin



Make sure it is on!!!

Section 6

STANDARD TCRX6-K

Standard TCRX6-K: Written policies and procedures are established and implemented for compounded non-sterile preparations that outline the use, maintenance and cleaning of compounding facilities that result in an environment that is appropriate to the scope of compounding performed by the pharmacy.

Interpretation: Written policies and procedures address cleaning and sanitization of the compounding areas and how they are documented.
The compounding facilities meet the following criteria:

- Adequate space for the orderly placement of equipment and materials to prevent mix-ups or cross contamination between ingredients, containers, labels, in-process materials, and finished preparations
- Designed to minimize unnecessary traffic
- Well-lighted with adequate heating, ventilation, and air conditioning

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Section 6

STANDARD TCRX6-K (CONTINUED)

- Adequate washing facilities including hot and cold water, soap or detergent, and air dryers or single-service towels
- Surfaces that contact pharmaceutical components, in-process materials, or finished preparations are not reactive, additive, or adsorptive to avoid altering the safety, identity, strength, quality, or purity of the preparation

WHAT IS WRONG WITH THIS GARB?

ADDITIONAL SECTION 6 STANDARDS

Standard TCRX6-L: Written policies and procedures are established and implemented in regard to compounding sterile preparations in accordance with USP Chapter <797> standards, the art and science of pharmacy, applicable laws and regulations.

Standard TCRX6-M: Non-Hazardous sterile preparations are compounded in an environment that meets requirements for the appropriate risk level as defined by USP Chapter Chapter <797>, state board of pharmacy regulations, and standards of good practice.

Standard TCRX6-N: Written policies and procedures are established and implemented in regard to how hazardous sterile preparations are compounded in an environment that meets requirements for the appropriate risk level as defined by USP Chapter <797>, state board of pharmacy regulations, and standards of good practice.

Standard TCRX6-O: Written policies and procedures are established and implemented for cleaning, disinfecting and monitoring the controlled air environment(s).

CLEANROOM MANAGEMENT

- Start with a properly designed environment!
  - Cleanroom should be designed to comply with USP <797> requirements
  - TCRX6-M lists some basic design requirements

California State Board of Pharmacy
March 21, 2014

CLEANROOM MANAGEMENT

- Some things do not belong in a cleanroom
  - Radios
  - Cardboard

What's wrong with this picture?

NOTES

NOTES

ALCOHOL – WHAT IS THE RIGHT KIND?

- Routine surface disinfection: sterile 70% alcohol
- Hand disinfection

USP<797> requires the use of a waterless alcohol-based surgical hand scrub with persistent activity

What is the difference? CDC guidelines for hand hygiene in health care settings

Surgical hand scrub: An antiseptic-containing preparation that substantially reduces the number of microorganisms on intact skin; it is broad-spectrum, fast-acting, and persistent

STERILE COMPOUNDING

- Surveyor will enter cleanroom
- Observe
  - Compounding
  - Disinfection
  - Labeling, etc.

- We are going to cover this in detail later!

Section 6

STANDARD TCRX6-L

Standard TCRX6-L: Written policies and procedures are established and implemented in regard to compounding sterile preparations in accordance with USP Chapter <797> standards, the art and science of pharmacy, applicable laws and regulations.

Interpretation: Personnel use appropriate techniques to compound preparations. Written policies and procedures are established and implemented to ensure preparations are made in accordance with applicable USP standards, the art and science of pharmacy, and applicable laws and regulations.

Written policies and procedures define how compounding is performed, including but not limited to:

- How critical processes are performed (including but not limited to weighing, measuring, and mixing)

Section 6

STANDARD TCRX6-L (CONTINUED)

- How dosage forms are prepared according to applicable USP standards, the art and science of pharmacy, and applicable laws and regulations
- Checks and rechecks for each procedure at each stage of the process
- Compounding preparations using the MFR, the Compounding Record, and associated written procedures, documenting any deviation in procedures
- Access to the buffer area is restricted to relevant personnel, and interruptions are minimized
- Introduction of only those medications, supplies, and equipment into the controlled air environments, which are necessary for the current preparation
- The use of carts in controlled air environments
- Proper aseptic technique, including attention to the concept of "first air"
- Cleaning and sanitizing compounding areas and equipment prior to compounding
- Segregating compounding activities to prevent mix-ups among ingredients, containers, labels, in-process materials, and finished preparations

Section 6

STANDARD TCRX6-L (CONTINUED)

- Performing compounding activities in a manner designed to prevent cross-contamination
- Clean room behaviors, including but not limited to food, gum, drinks, jewelry, rashes, sunburn, weeping sores, conjunctivitis, and active respiratory infection, etc.
- Thoroughly and promptly cleaning the compounding area and all equipment after use
- Avoiding interruption of personnel during the compounding process
- Personal hygiene, hand washing, gowning, and gloving for non-hazardous sterile compounding
- Preparing hazardous drugs, including using appropriate garb and biological safety cabinets (BSCs)
- Preparation of sterile drugs from non-sterile ingredients, if applicable
- Personnel are knowledgeable and follow the appropriate steps to ensure that preparations are made are in accordance with applicable USP standards, the art and science of pharmacy and applicable laws and regulations.

Section 6

STANDARD TCRX6-M

Standard TCRX6-M: Non-Hazardous sterile preparations are compounded in an environment that meets requirements for the appropriate risk level as defined by USP Chapter <797>, state board of pharmacy regulations, and standards of good practice.

Interpretation: The pharmacy has the proper environment(s) for the preparation of compounded sterile preparations (CSPs), which at a minimum, meet the USP Chapter <797>, applicable board of pharmacy requirements and standards of good practice appropriate to the risk level of CSPs it prepares, including but not limited to:

- Low risk non-hazardous or radiopharmaceutical preparations with a 12-hour or less beyond-use-date: A primary engineering control, ISO class 5 primary engineering control, (Compounding aseptic isolator (CAI), Compounding aseptic containment isolator (CACI), Biological Safety Cabinet (BSC) or Laminar Flow Workstation (LAFW)) located outside of a minimum ISO-7 area

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Section 6

STANDARD TCRX6-M (CONTINUED)

- Low and medium risk preparations: A ISO class 5 primary engineering control (CAI, CACI, BSC, LAFW) located in an ISO class 7 buffer area with an ISO class 7 or 8 ante-area. For buffer areas not physically separated from ante-areas a minimum airflow of 40 feet per minute is maintained across the line of demarcation

or

- A CAI or CACI meeting the following requirements:
  - The device provides isolation from the room and maintains ISO class 5 during dynamic operating conditions
  - Particle counts sampled approximately 6 to 12 inches upstream of the critical exposure site maintain ISO Class 5 levels during compounding operations
  - Not more than 3520 particles (0.5 µm and larger) per m3 shall be counted during material transfer, with the particle counter probe located as near to the transfer door as possible without obstructing the transfer

Section 6

STANDARD TCRX6-M (CONTINUED)

- The pharmacy has documentation from the manufacturer that the CAI/CACI will meet the above requirements when located in environments where the background particle counts exceed ISO Class 8
- Low, medium and high risk preparations: An ISO class 5 primary engineering control (CAI, CACI, BSC, LAFW) located in an ISO class 7 buffer area with an ISO class 7 or 8 ante-area; ante-areas and buffer rooms are physically separated, and maintain a minimum differential positive pressure of at least 0.02-0.05 inch water column.
- For high-risk preparations, pre-sterilization procedures are performed in a minimum ISO class-8 area.
- The surfaces of ceilings, walls, floors, fixtures, furniture, shelving, counters, and cabinets in the buffer area are impervious, free from cracks, crevices, and rust, are non-shedding, and resistant to disinfectants
- Facilities are comfortable and can maintain a temperature of 68 degrees Fahrenheit or cooler
- Buffer areas do not contain sinks or floor drains

Section 6

STANDARD TCRX6-N

Standard TCRX6-N: Written policies and procedures are established and implemented in regard to how hazardous sterile preparations are compounded in an environment that meets requirements for the appropriate risk level as defined by USP Chapter <797>, state board of pharmacy regulations, and standards of good practice.

Interpretation: Written policies and procedures define appropriate garb and personal protective equipment (PPE) (e.g. gowns, face masks, eye protection, hair covers, shoe covers, and double gloving with sterile chemotherapy gloves) to compound hazardous preparations per current The National Institute of Occupational Safety and Health (NIOSH) list of Antineoplastic and other hazardous drugs in a healthcare setting.

The pharmacy has the proper environment(s) to prepare sterile preparations which, at a minimum, meet the USP Chapter <797>, applicable board of pharmacy requirements and standards of good practice appropriate to the risk level of its CSPs, including but not limited to:

Section 6

STANDARD TCRX6-N (CONTINUED)

- Pre-sterilization procedures such as weighing, mixing and other manipulations are performed in a minimum Class I BSC in an ISO class-8 area
- Hazardous sterile preparations are compounded in an appropriate primary engineering control such as an ISO Class 5 BSC or CACI
- The ISO Class 5 or better BSC or CACI is placed in an ISO Class 7 or better area that is physically separated and has not less than 0.01- inch water column negative pressure to the adjacent ISO Class 7 or better anteroom
- In facilities that prepare a low volume of hazardous drugs, the use of two tiers of containment (e.g., closed system vial transfer device CSTD within a BSC or CACI that is located in a non-negative pressure room) is acceptable in lieu of a negative pressure room
- If a CACI meeting USP Chapter <797> requirements is used outside of a buffer area, the room area must maintain at least 0.01 inch water column negative pressure and 12 air changes per hour (ACHs)
- Facility protocols for decontamination of work surfaces that may come in contact with hazardous drugs

Section 6

STANDARD TCRX6-O

Standard TCRX6-O: Written policies and procedures are established and implemented for cleaning, disinfecting, and monitoring the controlled air environment(s).

Interpretation: Cleaning, disinfection and monitoring procedures follow requirements set forth by USP General Chapter <797> and the individual state boards of pharmacy. Written policies and procedures include, but are not limited to:

- Processes for cleaning/disinfecting work surfaces, equipment, and work areas including frequency, cleaners/disinfectants and documentation/logs
- Processes for certification of primary and secondary engineering controls at a minimum of every six months, and for the review and documentation of the results
- Processes for monitoring and recording pressure differentials between buffer area and ante-area, and between the ante-area and the general environment

Section 6

STANDARD TCRX6-O (CONTINUED)

- A program for viable air sampling meeting USP Chapter <797> requirements, including use of active air sampling equipment at a minimum of every six months, definition of sampling locations, method of collection, volume of air sampled, activity in the compounding area during sampling, and action levels
- Documentation of viable air sampling results
- Regardless of the colony forming unit (cfu) identified by airborne particle sampling, identification of microorganisms recovered (at least the genus level) and measures to be taken when pathogenic organisms are identified
- Action levels based on cfu counts for microbial contamination and measures to be taken when action levels are met or exceeded

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Section 6

STANDARD TCRX6-0 (CONTINUED)

- Requirements for a surface sampling program meeting USP Chapter <797> requirements, which include, but are not limited to:
  - Definition of sampling locations
  - Method of collection
  - Sampling frequency
  - Action levels
- Action levels based on cfu count

STERILE COMPOUNDING ENVIRONMENT

Must properly maintain and monitor sterile compounding environments.

- Timely, appropriate, and documented
- Cleanroom and Primary Engineering Control (PEC) certifications
- Surface and air sampling
- Pre-filters and other routine maintenance
- Temperature and humidity is monitored and controlled
- Cleaning and disinfection
  - Do you rotate disinfectants?
  - Do you use a sporicidal agent?
  - Do you allow appropriate dwell times?
  - Do you log the cleaning/disinfection and the disinfectant?

CLEANROOM CERTIFICATION IS A PROBLEM!

- Certified ISO 7 or 8 without High-Efficiency Particulate Air (HEPA) filters
  - PECs cannot be sole source of HEPA air
- Testing done under static conditions
- No smoke testing
- Room meets ISO requirements, but pharmacy ignores viable air counts
  - "Triple clean and carry on" is not an appropriate response
- Certifier does not perform certain required tests
  - Smoke testing
  - Leak tests
- PIC is ultimately responsible for reviewing certifications!

CLEANROOM MANAGEMENT: AUDIENCE POLL

My air sampling results did not exceed USP cfu limits, so I do not have to do anything. True or False?

Pathogens
Gram Negative Rods
Coagulase Positive Staph
Mold
Yeast

False!!!

USP <797> requires: Regardless of the colony forming unit (cfu) identified by airborne particle sampling, microorganisms recovered (at least the genus level) must be identified and measures taken when pathogenic organisms are identified.

CLEANROOM-RELATED PROBLEM AREAS

- No written Standard Operating Procedures (SOPs) for compounding procedures
- Items located in buffer area that are not directly necessary for sterile compounding (radios, CD players, etc.)
- Trash/sharps containers placed against laminar flow intakes
- Poorly designed environmental controls (e.g., no delineation in ante-room where non-covered shoes cannot enter, sink located outside ante-room, and positive pressures not consistent with USP <797>)
- Pre-sterilization procedures for high-risk preps in non-ISO areas

NON-STERILE COMPOUNDERS

- You may look up from your electronic devices now!

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Section 6

STANDARD TCRX6-P

Standard TCRX6-P: Written policies and procedures are established and implemented in regard to assigning each non-sterile preparation a Beyond-Use Date (BUD) to ensure that the preparation retains its strength, purity, and quality until the labeled BUD date.

Interpretation: Written policies and procedures are established and implemented to ensure that an appropriate BUD is assigned to each non-sterile preparation, which includes:

- When the pharmacy lacks stability information that is applicable to a specific drug and preparation, BUDs for non-sterile preparations are assigned using USP Chapter <795> "General Guidelines for Assigning Beyond-Use Dates"
- For Non-aqueous Formulations—The BUD is not later than the time remaining until the earliest expiration date of any API or six months, whichever is earlier
- For Water-Containing Oral Formulations—The BUD is not later than 14 days when stored at controlled cold temperatures

Section 6

STANDARD TCRX6-P (CONTINUED)

- For Water-Containing Topical/Dermal and Mucosal Liquid and Semisolid Formulations—The BUD is not later than 30 days
- When BUDs are assigned that exceed USP Chapter <795> "General Guidelines for Assigning Beyond-Use-Dates," the rationale for the BUD assignment is based upon the following in order of priority:
  - Stability information delivered from validated testing of the specific preparation, conditions, and container
  - USP/NF Monographs
  - Published stability information for similar compounds and formulations with the specific container and conditions
  - Stability studies published in literature (peer reviewed preferred)
  - Manufacturer (if a manufactured product is involved)
  - Professional judgment

Section 6

STANDARD TCRX6-P (CONTINUED)

- The rationale/source for the BUD assignment is documented on the MFR
- Compounded preparations are packaged in a manner that maintains their identity, strength, quality, and purity until the labeled BUD

Personnel should be aware that potency tests are designed to determine how much of the active drug is in the sample, whereas stability tests are used to determine a BUD for the preparation.

Note: Relationship between <795> and <797> in regard to BUDs was struck in 2014!!!

Section 6

STANDARD TCRX6-Q

Standard TCRX6-Q: Written policies and procedures are established and implemented in regard to assigning each sterile preparation a Beyond-Use Date (BUD) to ensure that the preparation retains its strength, purity, and quality until the labeled BUD date.

Interpretation: Written policies and procedures are established and implemented to ensure that an appropriate BUD is assigned to each sterile preparation, which includes:

- When the pharmacy lacks stability information that is applicable to a specific drug and preparation, BUDs for sterile preparations are assigned using USP Chapter <797> guidelines for each CSP risk level:
- Low-risk preparations: In the absence of passing a sterility test, storage periods before administration cannot exceed 48 hours at controlled room temperature, 14 days at a cold temperature, or 45 days frozen

Section 6

STANDARD TCRX6-Q (CONTINUED)

- Medium-risk preparations: In the absence of passing a sterility test, storage periods before administration cannot exceed 30 hours at controlled room temperature, 9 days at a cold temperature, or 45 days frozen
- High-risk preparations: In the absence of passing a sterility test, storage periods before administration cannot exceed 24 hours at controlled room temperature, 3 days at a cold temperature, or 45 days frozen

When BUDs are assigned that exceed USP Chapter <797> guidelines, the rationale for the BUD assignment is based upon the following in order of priority

- Stability information derived from validated testing of the specific preparation, conditions, and container
- USP/NF Monographs
- Published stability information for similar compounds and formulations with the specific container and conditions

Section 6

STANDARD TCRX6-Q (CONTINUED)

- Stability studies published in literature (peer reviewed preferred)
- Manufacturer (if a manufactured product is involved)
- Professional judgment
- The rationale/source for the BUD assignment is documented on the MFR
- Compounded preparations are packaged in a manner that maintains their identity, strength, quality, and purity until the labeled BUD
- Personnel should be aware that potency tests are designed to determine how much of the active drug is in the sample, whereas stability tests are used to determine a BUD for the preparation

NOTES

NOTES

MIND YOUR BUDs

- Default USP BUDs are listed in TCRX6-Q
- If defaults are exceeded, you must document the source of the BUD data:
  - Stability testing of your formulation/container (Potency≠Stabilitiy)
  - USP/NF Monographs
  - Published stability information for similar compounds
  - Manufacturer
  - Professional judgment
    - "In my professional judgment, all my compounds are good for a year"
- Rationale for BUD is documented on the MFR

STANDARD TCRX6-R

Standard TCRX6-R: Written policies and procedures are established and implemented to ensure preparations adhere to requirements for sterility and endotoxin limits.

Interpretation: This standard only applies to pharmacies that:

- Assign BUDs that exceed USP defaults for each risk level
- Prepare high-risk compounded sterile products (CSPs)
- Written policies and procedures are established and implemented to ensure that preparations adhere to established and/or compendial requirements for sterility requirements and endotoxin limits, which include:
  - Sterilization by filtration
  - Filters incorporate a 0.2 micron pore membrane that is chemically and physically compatible with the CSP. Filters are approved for human-use applications in sterilizing pharmaceutical fluids

STANDARD TCRX6-R (CONTINUED)

- Filters are of a size and capacity that permit the entire volume to be filtered without replacement
- An integrity test (e.g., bubble point test) is performed on each filter after use. The integrity test follows manufacturer's recommendations and is documented on the compounding record

Sterilization by steam

- Testing is performed to verify that the mass of containers to be sterilized will be sterile after the selected exposure duration in the particular autoclave
- Containers are placed to ensure that live steam contacts all ingredients and surfaces to be sterilized
- Pass solutions are passed through a 1.2 micron or smaller pore size filter into final containers to remove particulates before sterilization

Section 6

STANDARD TCRX6-R (CONTINUED)

- The effectiveness of steam sterilization is verified using appropriate biological indicators. The testing and results are documented

Sterilization by dry heat

- Dry heat is only used for those materials that cannot be sterilized by steam
- Containers are placed to ensure circulation of hot air over all ingredients and surfaces to be sterilized
- Dry heat sterilization is performed in a device designed for sterilization and capable of distributing heated air evenly throughout the chamber with a blower device
- The effectiveness of dry heat sterilization is verified using appropriate biological indicators; the testing and results are documented

Section 6

STANDARD TCRX6-R (CONTINUED)

Sterility testing

- When BUDs are assigned that exceed USP Chapter <797> defaults for CSPs in the absence of a sterility test, sterility is verified by USP Chapter <71>, equivalent, or superior sterility testing
- The testing and results are documented

Endotoxin testing

- All high-risk-level CSPs, except those for inhalation and ophthalmic administration, that are prepared in groups of more than 25 identical individual single-dose packages or in multiple-dose vials (MDVs) for administration to multiple clients/patients or that are exposed longer than 12 hours at 2° to 8° and longer than six hours at warmer than 8° before they are sterilized are tested to ensure that they do not contain excessive bacterial endotoxins
- The testing results are documented

Section 6

STANDARD TCRX6-R (CONTINUED)

Depyrogenation

- Dry heat depyrogenation or an equivalent, superior depyrogenation method is used to render glassware and other containers and utensils free of pyrogens and viable microorganisms
- The specific heat depyrogenation cycle and duration for specific load items is included in written documentation
- The effectiveness of dry heat depyrogenation is verified using endotoxin challenge vials. The vials are tested to verify that the cycle can produce a 3-log reduction in endotoxins

NOTES

NOTES

USP <71> - STERILITY TESTS

- PCAB standards require sterility testing to be in compliance with USP <71>
- Sterility testing has inherent problems
  - Can organisms grow under the conditions of the test?
  - What is the right test?
  - Does the sample size provide an appropriate estimate of sterility of the lot?

METHOD SUITABILITY

"If the product is contaminated, will the test show it?"

METHOD SUITABILITY

- Inoculate with 6 microorganisms
- Incubate NMT 3 days for bacteria, 5 days for fungi
- Looking for the presence of growth

Fluid Thioglycollate	Soybean-Casein Digest
Staphylococcus aureus	*Candida albicans*
Pseudomonas aeruginosa	*Aspergillus brasiliensis*
Clostridium sporogenes	*Bacillus subtilis*

METHOD SUITABILITY

- Should be done for ALL FORMULATIONS undergoing sterility testing
- Test highest concentration of each ingredient

TYPE OF TEST USP<71>

- Membrane Filtration
  - To be used whenever the nature of the product permits!
- Direct Inoculation
- Both must include negative controls

ALTERNATE STERILITY TESTS

- Must be demonstrated as at least as effective and reliable *USP Membrane Filtration or USP Direct Inoculation of the Culture Medium*
- *<1223> Validation of Alternative Microbiological Methods*

NOTES

NOTES

BRYCE, 1956

- *"The most that can be claimed is a probability that the product is sterile…"*
- *"The designation sterile is therefore to a certain extent arbitrary…"*

Percent Infected in Batch of 500, 1 organism	Proportion Pass as Sterile
1	99.1
2	96.7
5	84
10	58
20	36
25	20
30	11

USP <71> - TESTING QUANTITY

Table 3. Minimum Number of Articles to be Tested in Relation to the Number of Articles in the Batch

Number of Items in the Batch	Minimum Number of Items to be Tested for Each Medium (unless otherwise justified and authorized)
Parenteral Preparations	
Not More than 100 Containers	10% or 4 Containers, whichever is greater
More than 100 but not more than 500 containers	10 Containers
More than 500 containers	2% or 20 containers, whichever is less

USP <71> - TESTING QUANTITY

Table 3. Minimum Number of Articles to be Tested in Relation to the Number of Articles in the Batch

Number of Items in the Batch	Minimum Number of Items to be Tested for Each Medium (unless otherwise justified and authorized)
Ophthalmic and other non-injectable preparations	
Not more than 200 Containers	5% or 2 containers, whichever is greater
More than 200 containers	10 containers
Bulk solid products	
Up to 4 containers	Each container
More than 4 containers, but not more than 50 containers	20% or 4 containers, whichever is greater
More than 50 containers	2% or 10 containers, whichever is greater

USP <71> - TESTING QUANTITY

Table 2. Minimum Quantity to be Used for Each Medium

Quantity per container	Minimum Quantity to be Used (unless otherwise justified and authorized)
Liquids	
Less than 1 mL	The whole contents of each container
1-40 mL	Half the contents of each container, but not less than 1 mL
Greater than 40 mL, and not greater than 100 mL	20 mL
Greater than 100 mL	10 % of the contents of the container, but not less than 20 mL
Antibiotic liquids	1 mL

If each article does not contain sufficient quantities for each medium, use twice the number of articles indicated in Table 3.

USP<71>

- USP sterility testing is **DESTRUCTIVE**
  - Final dosing container is to be tested; this helps ensure the complete process is validated
    - Drug
    - Handling
    - Final container
  - Adding processes AFTER testing is not truly representative

Section 6

STANDARD TCRX6-S

Standard TCRX6-S: The organization ensures that pharmaceuticals are stored under appropriate conditions of sanitation, light, and temperature in the client's/patient's home.

Interpretation

- Pharmaceuticals dispensed to the client/patient are clearly labeled with the appropriate storage conditions requirements
- The organization educates the client/patient on the appropriate conditions for the storage of pharmaceuticals in the home environment
- When necessary, the Pharmacist intervenes, as indicated, to ensure that appropriate conditions are achieved or maintained

NOTES

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Section 6

STANDARD TCRX6-T

Standard TCRX6-T: Written policies and procedures are established and implemented for participating in clinical research/experimental therapies and/or administering investigational drugs.

Interpretation: Written policies and procedures include, but are not limited to
- Informing clients/patients of their responsibilities
- Informing clients/patients of their right to refuse investigational drugs or experimental therapies
- Informing clients/patients of their right to refuse to participate in research and clinical studies
- Notifying clients/patients that they will not be discriminated against for refusal to participate in research and clinical studies
- Stating which personnel can administer investigational medications/treatments

Section 6

STANDARD TCRX6-T (CONTINUED)

- Describing personnel's role in monitoring a client's/patient's response to investigational medications/treatments
- Identifying the responsibility for obtaining informed consent
- Defining the use of experimental and investigational drugs and other atypical treatments and interventions

Section 6

STANDARD TCRX6-U

Standard TCRX6-U: Written policies and procedures are established and implemented to ensure that compounded preparations are labeled in accordance with applicable laws and regulations, USP standards, and standards of good practice.

Interpretation: Compounded preparations are labeled appropriately per state and federal laws and regulations, USP standards, and standards of good practice. At a minimum labels for compounded preparations include:
- Name, address, and phone number of the pharmacy
- Date prescription was filled
- Prescription number
- Patient's name and species (if applicable)
- Name and strength(s) of active ingredient(s)
- Quantity or total volume

Section 6

STANDARD TCRX6-U (CONTINUED)

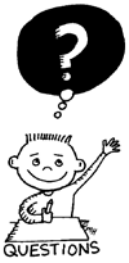
- Directions for use including the route of administration and rate of administration if applicable
- Prescriber's name
- Beyond-Use Date (BUD)
- Storage and handling instructions
- Notification that the preparation is compounded

CFST Only: When regulations permit an exemption to the above requirements, the pharmacy labels the compound with correct name and amount or concentration of ingredients, the total volume, the BUD, the appropriate route(s) of administration, the storage conditions, and other information for safe use.

SECTION 6 REVIEW

- Turn to page 6.18
  - Let's review the tools available
  - Great time to ask questions
  - Provided Tools Reflect Requirements

THAT'S ALL...SECTION 6



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Section 1

STANDARD TCRX1-A

Standard TCRX1-A: The organization is an established entity with legal authority to operate and has a physical location with the appropriate licensure, Articles of Incorporation, or other documentation of legal authority.

Interpretation: The organization is an established entity with legal authority to operate, and has the appropriate Articles of Incorporation, or other documentation of legal authority. Legal authority is granted to one individual, members of a Limited Liability Corporation (LLC), a Board of Directors (usually referred to as the governing body), and as allowed in state statutes for the appropriate type and structure of the organization. The entity, individual or organization has a copy of the appropriate documentation or authorization to conduct business.

If state or applicable local law requires a license or permit, the organization posts the current copy in a prominent spot in all locations/branches, and/or in accordance with appropriate regulations or laws.

Section 1

STANDARD TCRX1-A (CONTINUED)

The organization will display all licenses and/or permits required in the pharmacy operation in an area of public view.

- Resident state board of pharmacy permit/license
- Non-resident board of pharmacy permit/license as required, if applicable
- Drug Enforcement Administration (DEA) registration
- State controlled substance license, if applicable
- Pharmacist licenses
- Pharmacy technician licenses/certificates, if applicable
- Biohazard generator permit or appropriate contract as required
- The organization is in compliance with all applicable federal, state, and local laws and regulation and has access to the pharmacy rules and regulations of all states in which pharmacy services are provided

Section 1

STANDARD TCRX1-B

Standard TCRX1-B: The organization has access to relevant United States Pharmacopeia (USP) standards.

Interpretation: The pharmacy has access to current USP standards that are relevant to the scope of compounding performed.

Pharmacies that perform non-sterile compounding have access to relevant and current United States Pharmacopeia standards, including but not limited to USP Chapter <795>.

Pharmacies that perform sterile compounding have access to relevant and current United States Pharmacopeia standards including, but not limited to, USP Chapter <797>.

Section 1

STANDARD TCRX1-C

Standard TCRX1-C: The organization informs the accrediting body and other state/federal regulatory agencies, as appropriate, of negative outcomes from review/audits.

Interpretation: Negative outcomes affecting accreditation, licensure, or Medicare/Medicaid certification are reported to ACHC within 30 days of the occurrence. The report includes all actions taken and Plans of Correction (POCs).
Incidents reported to ACHC include, but are not limited to

- License suspension
- License probation; conditions/restrictions to license
- Non-compliance with Medicare/Medicaid regulations identified during survey by another regulatory body
- Civil penalties of ten thousand dollars ($10,000) or more
- Revocation of Medicare/Medicaid/third-party provider number

SECTION 1 COMPLIANCE

TOOLS AVAILABLE TO ASSIST WITH SECTION 1

- Section 1 Compliance Checklist (Page 1.5)
- Organizational Chart (Page 1.7)
- Process Analysis Checklist- Section 1 (Page 1.9)

Section 2

STANDARD TCRX2-A

Standard TCRX2-A: Written policies and procedures are established and implemented by the organization requiring that the client/patient be informed at the initiation of service on how to report complaints or grievances to the organization and/or ACHC.

Interpretation: The organization investigates and attempts to resolve all client/patient complaints/grievances and documents the results within a described time frame as defined in policies and procedures. Written policies and procedures include, but are not limited to:

- The appropriate person to be notified of the complaint/grievance
- Time frames for investigation activities, to include after hours
- Reporting of information
- Review and evaluation of the collected information
- Communication with the client/patient
- Documentation of all activities involved with the complaint/grievance, investigation, analysis, and resolution

NOTES

NOTES

TOOLS AVAILABLE TO ASSIST WITH SECTION 2

- Section 2 Compliance Checklist
- Client/Patient Complaint/Grievance Form
- Practice Run Audit Tool
- Process Analysis Checklist- Section 2

THE SINGLE MOST PROBLEMATIC AREA IS…

This issue has a tendency to affect the rest of your survey!!!!

PERSONNEL TRAINING/COMPETENCY

PCAB Section 3 (Page 3.1) Orientation/Training

- Written Policies and Procedures are required (TCRX3-A)
- The requirements are documented
- All the elements are covered
- Personnel competency is assessed
  - You cannot assume someone is competent because you trained them

Training ≠ Competency

Section 3

STANDARD TCRX3-A&B

Standard TCRX3-A/B: Written policies and procedures are established and implemented requiring all 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.

Interpretation: Written policies and procedures define the minimum education and training, licensure, certification, experience, and the minimum competencies required for each service offered, as well as the method for documenting that personnel have received the required training.

The organization designs and implements a competency assessment program based on the service provided. Competency assessment is an ongoing process and focuses on the primary service being provided. Competency assessment is conducted initially during orientation and annually thereafter. Verification of skills is specific to the employee's role and job responsibilities.

Section 3

STANDARD TCRX3-A&B

Policies and procedures are in place for determining that personnel are competent to provide quality service. Competency may be verified through observation, knowledge-based tests, and self-assessment. All competency assessments and training are documented. A self assessment tool alone is not acceptable. There is a plan in place for addressing performance and education of personnel when they do not meet competency requirements.

TRAINING AND COMPETENCY

- Three components
  - Orientation
  - Training
    - Hazardous drugs/PPE/spills
    - Equipment
    - Aseptic technique
  - Competency
    - Written testing – calculations (set pass/fail score)
    - Observation – use defined criteria (what action when criteria not met?)
    - Testing – potency, weight variance

NOTES

NOTES

USP <797> REQUIRED COMPETENCY ASSESSMENTS

- Testing
  - Initial garbing and gloving testing* (X 3)
  - Annual or biannual fingertip testing during media fill test*
  - Annual or biannual media fill tests
  - Note: sterility and potency testing can also be used!
- Competency Observation
  - Principle competency guidelines: Appendix I
  - Garbing and gloving assessment tool – Appendix III
  - Aseptic technique during media fill test assessment tool – Appendix IV
  - Cleaning and disinfection assessment tool – Appendix V
  - Hazardous drugs and PPE - no tool provided by USP <797>

*Note that USP<797> requires two types of fingertip testing

Section 3

STANDARD TCRX3-C

Standard TCRX3-C: Pharmacy personnel are trained to operate, clean, maintain, and calibrate compounding equipment.

Interpretation: Personnel responsible for compounding are trained and competent in the use of all equipment as applicable to their job description and/or assigned responsibilities.

Section 3

STANDARD TCRX3-D

Standard TCRX3-D: Pharmacy personnel are trained to perform routine cleaning and maintenance of equipment used in the client's/patient's home.

Interpretation: Personnel responsible for delivery, setup, pickup, and maintenance of equipment are trained and competent in the use of equipment used in the client's/patient's home.

Section 3

STANDARD TCRX3-E

Standard TCRX3-E: Written policies and procedures are established and implemented in regard to personnel who work with hazardous drugs receiving training and demonstrating competency in their storage, handling, and disposal.

Interpretation: Personnel who compound with hazardous drugs are trained in the identification, storage, handling, and disposal of these drugs. This training includes the use of personal protective equipment (PPE), safety equipment such as eye washes and spill kits, and engineering controls. The competency of personnel who handle hazardous drugs is assessed at least annually.

Personnel of reproductive capability confirm in writing that they understand the risk of handling hazardous drugs.

Section 3

STANDARD TCRX3-F

Standard TCRX3-F: Written policies and procedures are established and implemented in regard to personnel being trained and/or demonstrating competence to perform any new tasks/procedures prior to performing those tasks independently. Personnel are not allowed to perform any task for which they were evaluated as unsatisfactory.

Interpretation: Written policies and procedures define the process to ensure that personnel demonstrate competency in any new task before being assigned to perform that task. The organization also has a process to ensure that personnel are proven competent to perform tasks after re-training is provided.

Section 3

STANDARD TCRX3-G

Standard TCRX3-G: All pharmacy services are provided by qualified personnel and administered in accordance with the organization's policies and procedures, job descriptions, and each state board of pharmacy's rules and regulations where medications are shipped or dispensed.

Interpretation: Pharmacists and pharmacy technicians function in accordance with the organization's policies and procedures and job descriptions, accepted ethical and professional practice standards, and in accordance with all applicable federal, state, and local laws and guidelines set by the state board of pharmacy.

If medications are dispensed in other states, the pharmacy has the appropriate license/permits for those states serviced. Current copies of applicable rules and regulations are available.

NOTES

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Section 3

STANDARD TCRX3-H

Standard TCRX3-H: Written policies and procedures are established and implemented in regard to all pharmacy services being provided under the direction of a Registered Pharmacist who has documented training and competency in the scope of services provided.

Interpretation: All pharmacy services are provided under the direction of a Registered Pharmacist with sufficient education and experience in the scope of services offered.

Written policies and procedures identify the method and frequency for assessing the Pharmacist's competency in order to ensure that services are provided appropriately.

Section 3

STANDARD TCRX3-I

Standard TCRX3-I: The Registered Pharmacist supervises pharmacy technicians in accordance with the state board of pharmacy rules and regulations.

Interpretation: The pharmacy follows its state board of pharmacy regulations and the organization's policies and procedures that demonstrate that the Registered Pharmacist supervises the services provided by pharmacy technicians.

Section 3

STANDARD TCRX3-J

Standard TCRX3-J: Supervision is available during all hours that service is provided.

Interpretation: Supervision of personnel in the compounding pharmacy is provided 24 hours a day, 7 days a week, as applicable. Supervision is consistent with state laws and regulations.

Section 3

STANDARD TCRX3-K

Standard TCRX3-K: The organization's personnel have access to a reference library and/or internet access that is appropriate to the level of services provided.

Interpretation: Personnel have available a library of reference books, journals, internet access, etc., that is appropriate for the client/patient population served.

Resources include, but are not limited to:

- Professional journals
- General clinical reference
- Drug reference books
- Clinical guidelines
- Current medical dictionary
- Current statutes and rules for any state in which the personnel provide services

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TOOLS AVAILABLE TO ASSIST WITH SECTION 3

- Section 3 Compliance Checklist
- Job Description Template
- New Employee Orientation Checklist
- Personnel File Audit Tool
- Ongoing Personnel Assessment
- Compounding Competency
- Process Analysis Checklist- Section 3

p. 3.6

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RECORDS

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NOTES

NOTES

PATIENT RECORDS

- Initial assessments
  - Height and weight
  - Complete medication profile
  - Environmental component
  - The two following standards cover Section 4 Patient Records

STANDARD TCRX4-A

Standard TCRX4-A: A Registered Pharmacist reviews all client/patient medications and consults with other healthcare professionals caring for the client/patient, including the physician, as applicable. All Omnibus Budget Reconciliation Act (OBRA) counseling is completed as specified by law.

Interpretation: The pharmacy obtains the age, gender, allergies, species (for veterinary patients), medical conditions and pertinent information that may affect drug utilization. Prior to dispensing compounded medications a Pharmacist reviews all prescription and nonprescription medications that a client/patient is currently taking. A medication profile is established at the start of therapy. This profile is updated whenever there are changes in the client's/patient's medication therapy or as designated by the pharmacy policies and procedures.

A Registered Pharmacist is specifically responsible for recognizing the following as they pertain to compounded medications dispensed by the pharmacy:

- Side effects

STANDARD TCRX4-A (CONTINUED)

- Toxic effects
- Allergic reactions
- Desired effects
- Unusual and unexpected effects
- Actual or potential drug interactions
- Appropriateness of the drug for the client's/patient's diagnosis
- Appropriateness of the dose
- Changes in the client's/patient's condition that contraindicate continued use of the drug
- The Pharmacist, in conjunction with other health care professionals, is able to anticipate those effects that may rapidly endanger a client's/patient's life or wellbeing and instruct the client/patient in the prescribed regimen

Section 4

STANDARD TCRX4-B

Standard TCRX4-B: Written policies and procedures are established and implemented that address the timeliness of shipping, shipping errors, turnaround time, and lost shipments.

Interpretation: Written policies and procedures include, but are not limited to:

- Timeliness of shipping to ensure the client/patient receives medication prior to the administration date
- Ability to track the preparations after they leave the organization
- Notifying the client/patient if the shipment will be delayed
- Processes in place to ensure the client/patient has a continuous supply of medication if shipment is delayed or lost
- Personnel implement the policies and procedures for the process of tracking shipments

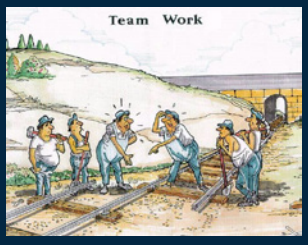
TOOLS AVAILABLE TO ASSIST WITH SECTION 4

- Section 4 Compliance Checklist
- Client Record Audit Tool (Reference Only)
- Process Analysis Checklist- Section 4

p. 4.3

ACCREDITATION UNIVERSITY

OVERVIEW OF PERFORMANCE IMPROVEMENT (PI) STANDARDS
(SECTION 5)



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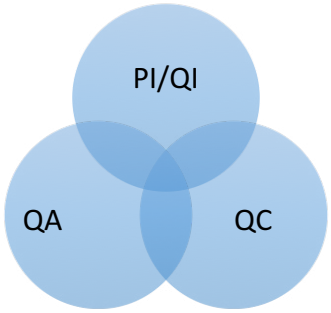
OVERVIEW OF PERFORMANCE IMPROVEMENT (PI) STANDARDS



DEFINITION CONFUSION

- Quality Assurance (QA), Quality Control (QC), and PI are not the same thing
- They do overlap
- PI incorporates both QA and QC but more than QA and QC are required
- To add to the confusion, the terms are often used interchangeably

AMERICAN SOCIETY FOR QUALITY DEFINITIONS

- Quality Assurance is *"the planned and systematic activities implemented in a quality system so that quality requirements for a product or service are fulfilled."*
  - Translation: The things you do to ensure that your preparations turn out the way you want them to
- Audience: Give some examples of QA in the typical pharmacy

ACHIEVING PCAB ACCREDITATION

AMERICAN SOCIETY FOR QUALITY DEFINITIONS

- Quality Control is "*…the observation techniques and activities used to fulfill requirements for quality.*"
  - Translation: The things you do to verify that your preparations turn out the way you want them to
- Audience: Give some examples of QC in the typical pharmacy

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AMERICAN SOCIETY FOR QUALITY DEFINITIONS

- Quality Improvement is "*an ongoing effort to improve products, services or processes. These efforts can seek 'incremental' improvement over time or 'breakthrough' improvement all at once.*"
- Audience: Give some examples of QI in the typical pharmacy

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DEFINITION CONFUSION

- Quality Assurance (QA), Quality Control (QC), and PI are not the same thing
- They do overlap
- PI incorporates both QA and QC, but more than QA and QC are required
- To add to the confusion, the terms are often used interchangeably

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Section 5

STANDARD TCRX5-A

Standard TCRX5-A: The organization develops, implements, and maintains an effective, ongoing, organization-wide Performance Improvement (PI) Program.

Interpretation: Each organization develops a program that is specific to its needs. The methods used by the organization for reviewing data include, but are not limited to:

- Current documentation (e.g., review of client/patient records, incident reports, and complaints)
- Direct observation
- Interviews with personnel
- The data collected by the organization for self-assessment includes, but is not limited to:
  - Adverse events

Section 5

STANDARD TCRX5-A (CONTINUED)

- Client/patient complaints
- Client/patient records
- At least one important aspect related to the service provided
- Ongoing monitoring of processes that involve risks, including infections and communicable diseases

Section 5

STANDARD TCRX5-B

Standard TCRX5-B: The organization ensures the implementation of an organization-wide Performance Improvement (PI) Plan by the designation of a person responsible for coordinating PI activities.

Interpretation: Duties and responsibilities relative to PI coordination include:

- Assisting with the overall development and implementation of the PI Plan
- Assisting in the identification of goals and related client/patient outcomes
- Coordinating, participating in and reporting of activities and outcomes
- The individual responsible for coordinating PI activities may be the owner, manager, supervisor or other designated personnel

Section 5

STANDARD TCRX5-C

Standard TCRX5-C: There is evidence of personnel involvement in the Performance Improvement (PI) process.

Interpretation: Personnel receive training related to PI activities and their involvement. Training includes, but is not limited to:

- The purpose of PI activities
- Person responsible for coordinating PI activities
- Individual's role in PI
- PI outcomes resulting from previous activities

Personnel are involved in the evaluation process through carrying out PI activities, evaluating findings, recommending action plans, and/or receiving reports of findings.

Section 5

STANDARD TCRX5-D

Standard TCRX5-D: Each Performance Improvement (PI) activity or study contains the required items.

Interpretation: Each PI activity/study includes the following items:

- A description of indicator(s) to be monitored/activities to be conducted
- Frequency of activities
- Designation of who is responsible for conducting the activities
- Methods of data collection
- Acceptable limits for findings
- Designation of who will receive the reports
- Plans to re-evaluate if findings fail to meet acceptable limits
- Any other activities required under state or federal laws or regulations

SAMPLE PI AUDIT


PI AUDIT DESCRIPTIONS

PI Activity/Audit Descriptions

Area to Be Audited/Monitored:

Description of Audit/Indicators:

Frequency:

Conducted By:

Data Collected From:

Threshold/Goal:

5.15, 5.21

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Section 5

STANDARD TCRX5-E

Standard TCRX5-E: Written policies and procedures are established and implemented by the organization to identify, monitor, report, investigate, and document all adverse events, incidents, accidents, variances, or unusual occurrences that involve clients/patients who receive compounded preparations.

Interpretation: Written policies and procedures describe the process for identifying, reporting, monitoring, investigating, and documenting all adverse events, incidents, accidents, variances, or unusual occurrences. Policies and procedures include, but are not limited to:

- Action to notify the supervisor or after hours personnel
- Time frame for verbal and written notification
- Appropriate documentation and routing of information

Section 5

STANDARD TCRX5-E (CONTINUED)

- Guidelines for notifying the physician, if applicable
- Follow-up reporting to the administration/board/owner

The organization investigates all adverse events, incidents, accidents, variances, or unusual occurrences that involve client/patient services and develops a POC to prevent the same or a similar event from occurring again. Events include, but are not limited to:

- Unexpected death
- A serious injury
- Significant adverse drug reaction, if applicable
- Significant medication error, if applicable
- Other undesirable outcomes as defined by the organization
- Adverse client/patient care outcomes

Section 5

STANDARD TCRX5-E (CONTINUED)

- Client/patient injury, (witnessed and un-witnessed)
- There are written policies and procedures for the organization to comply with the FDA and state boards of pharmacy to facilitate any recall notices submitted by the manufacturer, if applicable.
- The organization has developed a standardized form it uses to report adverse events and to document all incidents, accidents, variances, and unusual occurrences. The organization initiates an investigation within 24 hours after becoming aware of an incident resulting in a client's/patient's hospitalization or death. For other occurrences, the organization investigates within 72 hours after being made aware of the incident, accident, variances or unusual occurrences.
- This data is included in the PI plan. The organization assesses and utilizes the data to reduce further safety risks.

Section 5

STANDARD TCRX5-F

Standard TCRX5-F: Performance Improvement (PI) activities include an assessment of processes that involve risks, including infections and communicable diseases.

Interpretation: A review of all variances, which includes but is not limited to incidents, accidents and complaints/grievances, is conducted at least quarterly to detect trends and create an action plan to decrease occurrences.

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Section 5

STANDARD TCRX5-G

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

Interpretation: The pharmacy establishes an ongoing quality control program that defines:

- When to test preparations
- What test(s) should be performed
- Appropriate methods and equipment to use
- How to interpret the test
- Limits of the test
- Specific actions required when a preparation does not meet the test
- How quality control information is used to improve the performance of personnel
- How quality control information is incorporated into the pharmacy's PI Program

Section 5

STANDARD TCRX5-G (CONTINUED)

Testing every compounded preparation is not required; ACHC encourages organizations to design quality control programs that can be used to verify the quality of compounded preparations and the competency of compounding personnel. Below is an example for meeting compliance with this standard:

For non-sterile preparations:

- Using the procedure defined in USP Chapter <1163>, each compounder performs weight assessment for each of the following dosage forms they prepare: capsules, tablets, suppositories, inserts and lozenges every six months.
- Each compounder's finished preparation is tested for potency in each of the following dosage forms they prepare: solutions, suspensions, capsules, tablets, suppositories, creams/ointments and lozenges every six months.

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Section 5

STANDARD TCRX5-G (CONTINUED)

For sterile preparations:

- For accuracy and precision testing for automated compounding devices, a periodic assessment of large volume parenterals to verify fill volume is performed.
- For potency testing of finished preparations, each compounder's finished high risk preparation is tested for potency in each of the following dosage forms they prepare:
  - Preparations sterilized by filtration
  - Sterilization
  - Dry heat every six months
  - Sterility testing of high risk preparations is performed in accordance with USP Chapter <71>.
  - Inspection of low and medium risk preparations is performed for proper labeling, absence of cores/particulates ,etc.

Section 5

STANDARD TCRX5-H&I

Standard TCRX5-H/I: Performance Improvement (PI) activities include ongoing monitoring of at least one important aspect related to the non-sterile/sterile compounding process.

Interpretation: The organization conducts monitoring of at least one important aspect of the non-sterile/sterile compounding process. An important aspect of service reflects a dimension of activity that may be high volume (occurs frequently or affects a large number of clients/patients), high risk (causes a risk of serious consequences if the service is not provided correctly), or problem-prone (has tended to cause problems for personnel or clients/patients in the past).

Section 5

STANDARD TCRX5-J

Standard TCRX5-J: Performance Improvement (PI) activities include the ongoing monitoring of client/patient complaints/grievances.

Interpretation: PI activities include ongoing monitoring of client/patient complaints and the action(s) needed to resolve complaints and improve client/patient service.

Section 5

STANDARD TCRX5-K

Standard TCRX5-K: There is a written Plan of Correction (POC) developed in response to any Performance Improvement (PI) findings that do not meet an acceptable threshold as described in standard TCRX5-D (Acceptable limits for findings.

Interpretation: A written POC is developed in response to any PI activity that does not meet an acceptable threshold. The POC identifies changes in policies and procedures that will improve performance.

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Section 5

STANDARD TCRX5-L

Standard TCRX5-L: There is an annual Performance Improvement (PI) report written.

Interpretation: There is a comprehensive, written annual report that describes the PI activities, findings and corrective actions that relate to the service provided. In a large, multi-service organization, the report may be part of a larger document addressing all of the organization's programs.

While the final report is a single document, improvement activities must be conducted at various times during the year. Data for the annual PI report may be obtained from a variety of sources and methods, such as audit reports, client/patient questionnaires, feedback from referral sources and outside survey reports.

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CASE STUDY #1

PI AUDIT DESCRIPTIONS

PI Activity/Audit Descriptions

Description of Audit/Indicators:
Personnel records of sterile compounding personnel will contain:
*Result of fingertip testing every 6 months
*Results of an aseptic compounding validation test every 6 months

Conducted By: Sal Monella

Frequency of Activities:
Biannually, on January 2nd and July 31st

Data Collected From:
Personnel records

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CASE STUDY #1

Threshold/Goal:

100% of personnel records will contain the required information.

Plan for re-evaluation if threshold/goal is not met:

Personnel whose records do not meet requirements will be flagged for immediate corrective action. If not completed within 20 days, will be prohibited from performing further sterile compounding. QI coordinator will be notified of test completion.

All PI reports will be presented to the PI committee and the Governing Body/owner.
In the event an audit fails to meet a threshold/goal, a written plan of correction will be created that indicates plans to re-evaluate.

CASE STUDY #2

PI AUDIT DESCRIPTIONS

PI Activity/Audit Descriptions

Description of Audit/Indicators: Conducted By: S. Monella

Pharmacy errors will be documented and classified according to: wrong dose, wrong drug, wrong route/ form, allergy/interaction, incorrect labeling, wrong patient, wrong route. Incident reports will be filed in a binder under the appropriate tab.

Frequency of Activities:
Monthly at staff meetings

Data Collected From:
Incident reports

CASE STUDY #2

Threshold/Goal:

95% of all incidents will be properly documented. 100% of all incidents resulting in hospitalization, change of drug or a need for treatment as the result of the event will be documented and reported per policy 123 to the ISMP Patient Safety Organization.

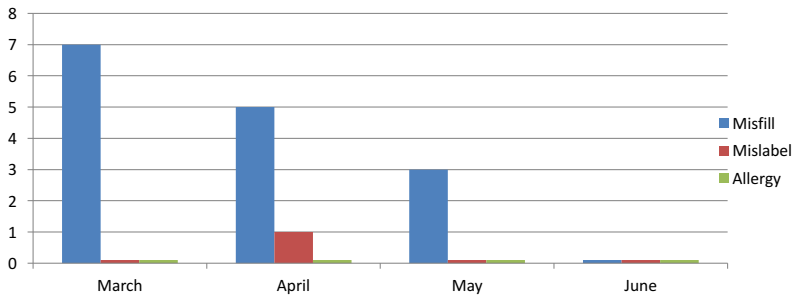
Plan for re-evaluation if threshold/goal is not met:

The initial step will be to retrain affected personnel and continue to monitor performance. Trends in findings will be used to improve organizational performance. Threshold to initiate action incident that involves the same individual or service failure two times in one month.

All PI reports will be presented to the PI committee and the Governing Body/owner.
In the event an audit fails to meet a threshold/goal, a written plan of correction will be created that indicates plans to re-evaluate.

ACHIEVING PCAB ACCREDITATION

INCIDENT REPORT - TRENDS



PLAN OF CORRECTIVE ACTION

PLAN OF CORRECTION

Plan of Correction

PI Activity Audit: Mislabeling errors Date: 5/29/14

Threshold/Goal: 0 mislabeled rxs per month Actual Result: 5/month

Possible Reasons Goal Not Met:
90% of the errors were a result of selecting similarly labeled and sized vials adjacent to each other in the refrigerator. Errors due to mispicks.

Corrective Plan of Action:
(List any policy & procedure changes, re-education, form changes, etc.)

ACTION ITEM	RESPONSIBLE PERSON
Conduct inservice on standard triple check	PIC
Separated similar vials in refrigerator and	
Labeled each with a different color	Chief Tech

ANNUAL SUBMISSION OF CONTINUED COMPLIANCE EVIDENCE

Why does PCAB have annual compliance requirements?

ACHC | PCAB PHARMACY COMPOUNDING ACCREDITATION BOARD

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STANDARD TCRX7-A

Standard TCRX7-A: Organizations that are PCAB Accredited for Non-Sterile Compounding are required to provide documentation as evidence of compliance on an annual basis. This documentation is submitted two months prior to each calendar year anniversary of your PCAB Accreditation. For example: if your accreditation cycle is 2/6/16 to 2/6/19, your annual compliance information should be sent to ACHC each December. (This is an informational standard only for providers applying for Non-Sterile Compounding for the first time.)

Interpretation: Organizations submit documentation annually to demonstrate continued compliance with PCAB Accreditation Non-Sterile Compounding requirements.

The following documentation is submitted to ACHC two months prior to each calendar year anniversary of your PCAB Accreditation. The documentation requirements are:

- A description of any compounding equipment that was added since the last ACHC visit, and evidence of staff training consistent with ACHC Standard TCRX3-A
- The total number of Pharmacists and pharmacy technicians performing non-sterile compounding

STANDARD TCRX7-A (CONTINUED)

- Submission of a summary of all calibration logs and certifications done on the non-sterile compounding equipment including balance calibrations consistent with ACHC Standard TCRX6-E
- Submission of a sample of 10 MFRs and Compounding Record(s) for a variety of preparation prepared over the previous 12 months consistent with ACHC Standard TCRX6-G and TCRX6-H
- Submission of initial (for new hires) and annual competency assessments (for existing personnel), consistent with ACHC Standards TCRX3-A and TCRX3-F
- Documentation of compliance with the quality control program defined by ACHC Standard TCRX5-G including a summary of internal testing results and copies of external potency testing results
- Submission of plans of correction as outlined in ACHC Standard TCRX5-K, including plans for correcting out of specification test results as a result of quality control testing performed under ACHC Standard TCRX5-G
- Submission of the annual PI report as outlined in ACHC Standard TCRX5-L

STANDARD TCRX7-B

Standard TCRX7-B: Organizations that are PCAB Accredited for Sterile Compounding are required to provide documentation as evidence of continued compliance on an annual basis. This documentation is submitted two months prior to each calendar year anniversary of your PCAB Accreditation. (For example: if your accreditation cycle is 2/6/16 to 2/6/19 your annual compliance information should be sent to ACHC each December.) (This is an informational standard only for providers applying for sterile compounding for the first time.)

Interpretation: Organizations submit documentation annually to demonstrate continued compliance with PCAB Accreditation Sterile Compounding requirements.

The following documentation is submitted to ACHC two months prior to each calendar year anniversary of your PCAB Accreditation. The documentation requirements are:

- A description of any compounding equipment that was added since the last ACHC visit, and evidence of staff training consistent with ACHC Standard TCRX3-B
- The total number of Pharmacists and pharmacy technicians performing sterile compounding

Section 7

STANDARD TCRX7-B (CONTINUED)

- Submission of initial (for new hires) and annual competency assessments (for existing personnel) as required under ACHC Standards TCRX3-B and TCRX3-F
- Submission of a summary of all calibration logs and certifications done on the sterile compounding equipment including balance calibrations, consistent with ACHC Standard TCRX6-E
- Submission of a sample of 10 Master Formulation Records (MFRs) and Compounding Record(s) for a variety of preparation prepared over the previous 12 months consistent with ACHC Standard TCRX6-G and TCRX6-H
- Documentation of compliance with the quality control program defined by ACHC Standard TCRX5-G including a summary of internal testing results and copies of external potency testing results
- Submission of POCs as outlined in ACHC Standard TCRX5-K, including plans for correcting out-of-specification test results as a result of quality control testing performed under ACHC Standard TCRX5-G

Section 7

STANDARD TCRX7-B (CONTINUED)

- Summary of records indicating compliance with the requirements of ACHC standard TCRX6-R in regard to sterility and endotoxin testing including, but not limited to: lot or batch number, quantity or volume prepared, units and/or volume tested, results of the test (s) and specific actions taken if the test(s) indicated the potential for microbiological contamination or excessive endotoxins.
- Submission of the annual PI report as outlined in TCRX5-L

TOOLS AVAILABLE TO ASSIST WITH SECTION 7

- Sterile Compounding Continued Compliance Packet
- Non-Sterile Compounding Continued Compliance Packet
- Process Analysis Checklist- Section 7

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MARKETING TOOLS

- ACHC provides the tools to leverage your accredited status
- All PCAB-accredited organizations receive the PCAB Branding Kit
  - Brand Guidelines
  - PCAB Accredited Logos
  - Sample Press Release Template
  - Window Cling

BRANDING ELEMENTS

- PCAB Accredited Logo
  - Represents compliance with the most stringent national standards

PCAB ACCREDITED®
Compounding Pharmacy
A SERVICE OF ACHC

BRANDING ELEMENTS

- PCAB Accredited Secondary Logo
  - Available for applications with limited space

PCAB ACCREDITED®
Compounding Pharmacy

PROMOTING YOUR PCAB ACCREDITED STATUS

- A few basic places to promote PCAB accredited status include:
  - Website – *Home page or dedicated landing page*
  - Marketing Materials - *Any marketing piece that is seen by the public*
  - Press Releases - *In the "boilerplate" of the press release, or the background information normally found toward the bottom of a press release*
  - Social Media - *Home page, banner image, or profile image*
  - Promotional Items - *Tradeshow displays, giveaways, binders, or folders*
  - Email - *Email signature*
  - Voicemail - *Voicemail message*

ACHC RESOURCES

- ACHC's Marketing Department is available to help with your marketing needs.
- Feel free to contact them at marketing@achc.org or (855) 937-2242.

QUESTIONS?

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NOW WHAT?

A) Analysis
- You have spent today with ideas running through your head
  - Only you know where you are and where you fall short
  - Develop a team approach to determine areas of need
  - Prioritize those items most critical to patient and staff safety

B) Audits
- Be the Surveyor; perform your own survey
- Use the audit tools provided

C) Corrective Action and Preventative Action (CAPA)
- Develop and document corrective and preventative actions
- Monitor areas of concern or high risk in your PI Program

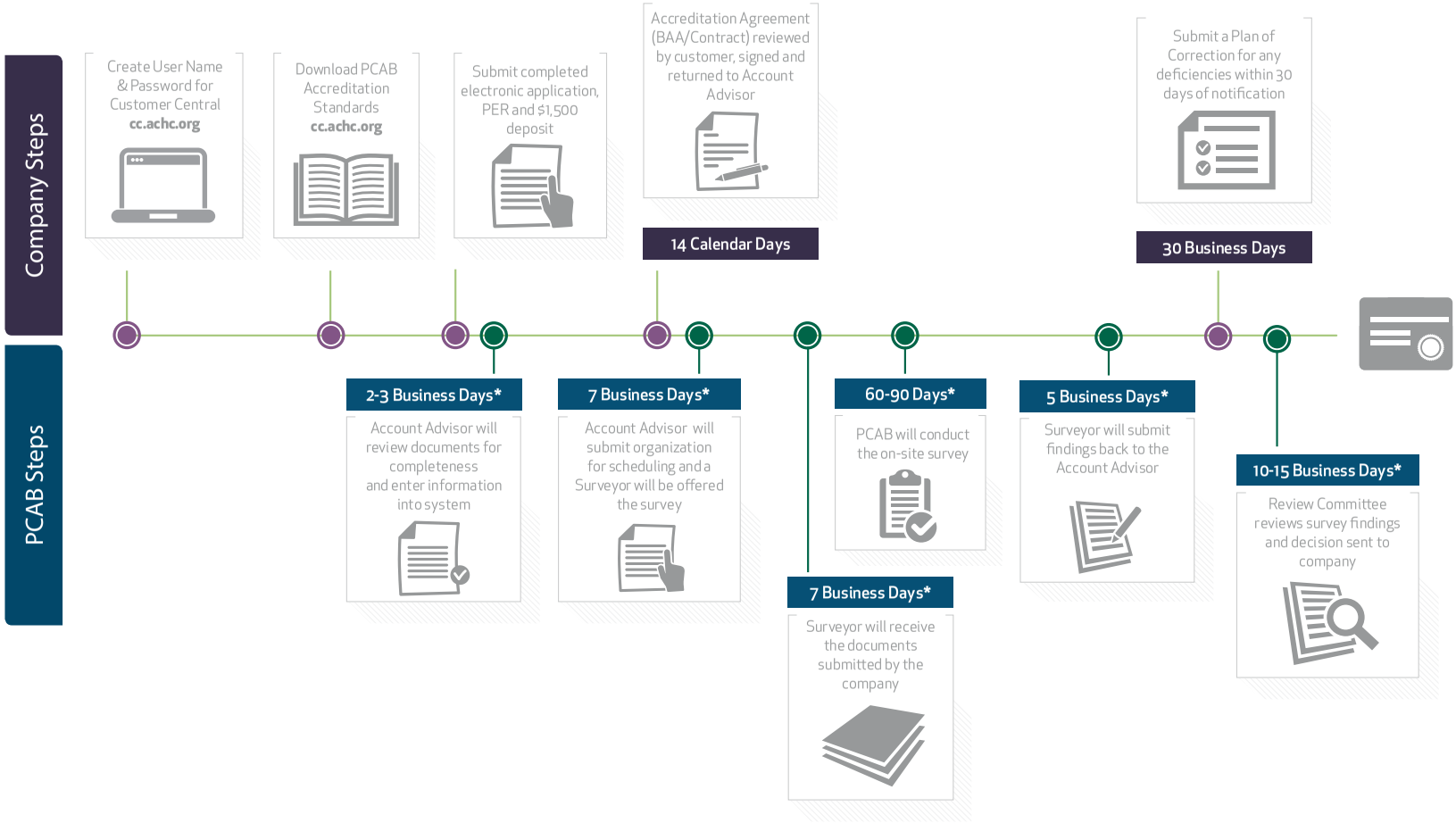
ACCREDITATION UNIVERSITY

ADDITIONAL RESOURCES

ACCREDITATION COMMISSION *for* HEALTH CARE

PHARMACY COMPOUNDING ACCREDITATION BOARD

ACCREDITATION PROCESS



*Approximately

PCAB PRELIMINARY EVIDENCE REPORT (PER) INITIAL CHECKLIST

[PHARMACY ACCREDITATION]

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.

Required items to be submitted to the Accreditation Commission for Health Care (ACHC):

- ☐ 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)

I, having the authority to represent this organization, verify that _____ (organization's legal name) has met the above requirements for survey. Failure to meet any of the aforementioned requirements when the ACHC Surveyor arrives on site may result in additional charges to the organization for a subsequent survey to be performed when the organization has notified ACHC it has met all of the above requirements. I agree that during my accreditation with ACHC that if my facility is under citation by any federal/state regulatory authority that I will notify ACHC within ten (10) calendar days.

_____ _____

(Name) (Title)

_____ _____

(Date) (Signature)

ACHC CROSSWALK

PHARMACY

THE FOLLOWING CROSSWALK PROVIDES A COMPARISON BETWEEN LEGACY PCAB STANDARDS (PRIOR TO JULY 1, 2014) AND REVISED PCAB STANDARDS (AFTER JULY 1, 2014).

Legacy PCAB Standard	Revised PCAB Standard
Standard 1.10 Facility: The pharmacy is licensed or registered with relevant state and federal regulatory authorities to operate a pharmacy and if applicable, dispense controlled substances. **Compliance Indicators**	**Standard TCRX1-A: The organization is an established entity with legal authority to operate and has a physical location with the appropriate licensure, Articles of Incorporation, or other documentation of legal authority.** **New requirement:** The pharmacy must display all required licenses and/or permits in an area of public view.
A. The pharmacy demonstrates that its employees have access to pharmacy rules and regulations of all states where pharmacy services are being provided.	Applicable personnel can demonstrate how they access rules and regulations of all states where pharmacy services are provided.
B. If the pharmacy has a pending regulatory action, it notifies PCAB® within thirty (30) days	**StandardTCRX1-C: The organization informs the accrediting body and other state/federal regulatory agencies, as appropriate, of negative outcomes from review/audits.** **Interpretation:** Negative outcomes affecting accreditation, licensure, or Medicare/ Medicaid certification are reported to ACHC within 30 days of the occurrence. The report includes all actions taken and plans of correction (POCs). Incidents reported to ACHC include, but are not limited to: • License suspension • License probation; conditions/restrictions to license • Non-compliance with Medicare/Medicaid regulations identified during survey by another regulatory body • Civil penalties of ten thousand dollars ($10,000.00) or more • Revocation of Medicare/Medicaid/third-party provider number
Standard 1.20 Personnel: All personnel including Pharmacists, technicians, students, temporary personnel, and those affiliated through contractual or other arrangements who are engaged in compounding and dispensing in the pharmacy are licensed, registered, certified, or otherwise credentialed, if applicable, by the states in which they practice, by an appropriate licensing agency, certifying agency, school of pharmacy, or other body.	**Standard TCRX3-A: 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.** **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.**

ACHC CROSSWALK

PHARMACY

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Legacy PCAB Standard	Revised PCAB Standard
Standard 1.30 External Standards: The pharmacy compounds according to standards of practice adopted by its state board of pharmacy and/or national practices and standards adopted by non-governmental standard setting organizations.	**Standard TCRX1-B: The organization has access to relevant United States Pharmacopeia (USP) standards.** **Interpretation:** The pharmacy has access to current USP standards that are relevant to the scope of compounding performed. Pharmacies that perform non-sterile compounding have access to relevant and current United States Pharmacopeia standards, including but not limited to USP Chapter <795>. Pharmacies that perform sterile compounding have access to relevant and current United States Pharmacopeia standards, including but not limited to USP Chapter <797>. **Note:** Also, see TCRX1-A which requires access to, and compliance with, state regulations.
Standard 1.40 Standard Operating Procedures: The pharmacy develops, maintains, follows, and periodically updates written Standard Operating Procedures (SOPs) which addresses all aspects of the compounding operation. **Compliance Indicators** **A.** The pharmacy provides a copy of its SOPs manual with a table of contents. **B.** The pharmacy demonstrates that the SOPs are readily available to and accessible by all relevant compounding personnel.	**Note:** Where appropriate, the revised standards incorporate specific Standard Operating Procedures (referred to as Policies and Procedures) into each standard.
C. The SOPs contain a "policy on policies" which may include: • Identification of the individual(s) in the organization that have authority to approve SOPs and subsequent edits to SOPs; • Outlining the process by which SOPs are approved; • Recording the date new polices are implemented; • Establishing and maintaining an indexing system to facilitate reference and retrieval of SOPs by staff; • Document the review, revision, and archiving of existing SOPs.	The revised standards do not have a requirement for the SOP required by indicator C.
New Requirement	**Standard TCRX2-A: Written policies and procedures are established and implemented by the organization requiring that the client/patient be informed at the initiation of service on how to report complaints or grievances to the organization and/or ACHC.** **Interpretation:** The organization investigates and attempts to resolve all client/patient complaints/grievances and documents the results within a described time frame as defined in policies and procedures.

ACHC CROSSWALK

PHARMACY

Legacy PCAB Standard	Revised PCAB Standard
Standard 2.10 General: Supervision and level of personnel is sufficient to assure the safety and integrity of compounding. All personnel affiliated with compounding in the pharmacy are competent to perform their assigned duties. **Compliance Indicators** **A.** The pharmacy provides a written description of the responsibilities and functions of all compounding personnel. **B.** The pharmacy has SOPs for orienting and training new compounding personnel, including temporary and contracted employees. **C.** The pharmacy has SOPs for educating, training, and assessing the competencies of all compounding personnel on an ongoing basis, including documentation that compounding personnel is trained on SOPs. **D.** The pharmacy demonstrates that it continually assesses its staffing needs relevant to all elements of the compounding and dispensing process including environmental and equipment maintenance.	**No new requirements.** Existing requirements have been clarified and divided into multiple standards for clarity . Review the full standards manual for complete compliance requirements for each standard below. **Standard TCRX3-A: 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.** **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.** **Standard TCRX3-C: Pharmacy personnel are trained to operate, clean, maintain, and calibrate compounding equipment.** **Standard TCRX3-D: Pharmacy personnel are trained to perform routine cleaning and maintenance of equipment used in the clients'/patients' home.** **Standard TCRX3-E: Written policies and procedure are established and implemented in regard to personnel who work with hazardous drugs receiving training and demonstrating competency in their storage, handling and disposal.** **Standard TCRX3-F: Written policies and procedures are established and implemented in regard to personnel being trained and/ or demonstrating competence to perform any new tasks/procedures prior to performing those tasks independently. Personnel are not allowed to perform any task for which they were evaluated as unsatisfactory.** **Standard TCRX3-G: All pharmacy services are provided by qualified personnel and administered in accordance with the organization's policies and procedures, job descriptions and each state board of pharmacy's rules and regulations where medications are shipped or dispensed.** **Standard TCRX3-I: The Registered Pharmacist supervises pharmacy technicians in accordance with the state board of pharmacy rules and regulations.** **Standard TCRX3-J: Supervision is available during all hours that service is provided.**

ACHC CROSSWALK

PHARMACY

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Legacy PCAB Standard	Revised PCAB Standard
Standard 2.20 Pharmacist in Charge: There is a Pharmacist in charge of the compounding activities who establishes the scope of compounding practice for relevant staff based on the education, training, and demonstrated competence. The Pharmacist in charge supervises all compounding personnel, assures that compounded preparations meet SOPs, and maintains compliance with state and federal regulations and PCAB® standards.	**Standard TCRX3-H: Written policies and procedures are established and implemented in regard to all pharmacy services being provided under the direction of a Registered Pharmacist who has documented training and competency in the scope of services provided.** **Interpretation:** All pharmacy services are provided under the direction of a Registered Pharmacist with sufficient education and experience in the scope of services offered.
New Requirement	Written policies and procedures identify the method and frequency for assessing the Pharmacist's competency in order to ensure that services are provided appropriately.
Standard 2.30 Staff Pharmacists: There are staff Pharmacists to assure that compounded preparations are prepared, packaged, labeled, stored, and dispensed according to SOPs of the pharmacy. Staff Pharmacists are responsible for patient counseling and/or patient care services required by applicable state law or practice standards.	Incorporated into standards TCRX3-A thru TCRX 3G, TCRX3-I and TCRX3-J
Standard 3.10 General: The pharmacy has facilities and equipment sufficient for the safe and accurate compounding of preparations. Compliance Indicators **A.** The pharmacy demonstrates that the size, type, and quality of facilities and equipment in the pharmacy is adequate to safely and accurately compound preparations in the amount and type relative to the nature of compounding that is performed in the pharmacy. This should include procedures for the control and containment of powders during compounding.	No new requirements. Existing requirements have been clarified and divided into multiple standards for clarity. Review the full standards manual for complete compliance requirements for each standard below. **Standard TCRX6-I: Written policies and procedures are established and implemented in regard to compounding non-sterile preparations in accordance with USP Chapter <795> standards, the art and science of pharmacy, and applicable laws and regulations.** **Standard TCRX6-K: Written policies and procedures are established and implemented for compounded non-sterile preparations that outline the use, maintenance, and cleaning of compounding facilities that result in an environment that is appropriate to the scope of compounding performed by the pharmacy.** **Standard TCRX6-L: Written policies and procedures are established and implemented in regard to compounding sterile preparations in accordance with USP Chapter <797> standards, the art and science of pharmacy, applicable laws and regulations.** **Standard TCRX6-M: Non-Hazardous sterile preparations are compounded in an environment that meets requirements for the appropriate risk level as defined by USP Chapter <797>, state board of pharmacy regulations, and standards of good practice.**

ACHC CROSSWALK

PHARMACY

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Legacy PCAB Standard	Revised PCAB Standard
B. The pharmacy has SOPs for each piece of equipment used in the compounding process that addresses cleaning, maintaining, calibrating, and verification according to compendial standards or manufacturers' standards. At a minimum, the SOPs include documentation that equipment is regularly cleaned, maintained, calibrated and verified according to compendial standards or manufacturers' standards.	**Standard TCRX6-E: Written policies and procedures are established and implemented by the pharmacy relating to the appropriate use, calibration, cleaning and as appropriate, disinfection or sterilization of equipment used for preparing, dispensing, labeling, and shipping of preparations.** **Interpretation:** The written policies and procedures and the implementation must include, but are not limited to: • Appropriate use of equipment • Calibration of machines and equipment that states frequency and findings • Cleaning schedules for equipment • Disinfection or sterilization procedures and schedules • Testing of equipment • Procedure for the use, calibration, maintenance, and accuracy testing of ACDs (applies to sterile compounding only)
C. If the pharmacy handles hazardous materials, it demonstrates that its SOPs are adequate to protect personnel based on volume and scope of compounding performed.	**Standard TCRX6-J: Written policies and procedures are established and implemented in regard to hazardous non-sterile compounded preparations and components being manipulated and prepared in, at minimum, a Class I biological safety cabinet (BSC).** **Interpretation:** Written policies and procedures are established and implemented in regard to hazardous compounded preparations and components being manipulated and prepared in, at minimum, a Class I BSC using appropriate garb and personal protective equipment (PPE), and for monitoring the proper operating conditions for all equipment used in accordance with manufacturer guidelines. **Standard TCRX6-N: Written policies and procedures are established and implemented in regard to how hazardous sterile preparations are compounded in an environment that meets requirements for the appropriate risk level as defined by USP Chapter <797>, state board of pharmacy regulations, and standards of good practice.** **Interpretation:** Written policies and procedures define appropriate garb and personal protective equipment (PPE) (e.g., gowns, face masks, eye protection, hair covers, shoe covers or dedicated shoes, and double gloving with sterile chemo-type gloves) to compound hazardous preparations.
Standard 3.11 References: The pharmacy maintains reference materials that are current and relevant to the compounding performed in the pharmacy and in accordance with state regulations. Reference materials are readily accessible to personnel responsible for compounding of preparations.	**Standard TCRX3-K: The organization's personnel have access to a reference library and/or internet access that is appropriate to the level of services provided.**

ACHC CROSSWALK

PHARMACY

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Legacy PCAB Standard	Revised PCAB Standard
Standard 3.20 Non-Sterile Compounding: The pharmacy that compounds non-sterile preparations maintains facilities that provide for minimization of interruptions, avoidance of contamination, and reduction of the potential for contamination of the compounded preparation. **Compliance Indicators** **A.** The pharmacy has a dedicated, exclusive area for general, non-sterile compounding that meets current USP <795> standards. **B.** The pharmacy demonstrates that it organizes work flow to minimize interruption of compounding staff during the compounding process. Traffic from employees not involved with compounding is minimized. **C.** The pharmacy demonstrates that it maintains facilities and procedures adequate to avoid cross-contamination and contamination by dust and other particulates in the compounding area. **D.** The pharmacy demonstrates that any equipment and surfaces involved in the compounding process is appropriately cleaned and/or sanitized before and after compounding activity as appropriate to prevent contamination. **E.** The pharmacy has SOPs for cleaning and maintaining equipment and for the establishment of cleaning and maintenance schedules.	**No new requirements.** Existing requirements were clarified and divided into multiple standards to for clarity. Review the full standards manual for complete compliance requirements for each standard below. **Standard TCRX6-I: Written policies and procedures are established and implemented in regard to compounding non-sterile preparations in accordance with USP Chapter <795> standards, the art and science of pharmacy, and applicable laws and regulations.** **Standard TCRX6-J: Written policies and procedures are established and implemented in regard to hazardous non-sterile compounded preparations and components being manipulated and prepared in, at minimum, a Class I biological safety cabinet (BSC).** **Standard TCRX6-K: Written policies and procedures are established and implemented for compounded non-sterile preparations that outline the use, maintenance, and cleaning of compounding facilities that result in an environment that is appropriate to the scope of compounding performed by the pharmacy.**

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Legacy PCAB Standard	Revised PCAB Standard
Standard 3.30 Sterile Compounding: The pharmacy that compounds sterile preparations maintains facilities that provide for minimization of interruption, avoidance of contaminations, and an exclusive area for compounding of sterile preparations. **Compliance Indicators** **A.** The pharmacy has an area for aseptic compounding of sterile preparations that meets current USP <797> standards. **B.** The pharmacy demonstrates that it organizes work flow to minimize interruption of compounding staff during the compounding process. Traffic from employees not involved with compounding is minimized. **C.** The pharmacy demonstrates that it maintains facilities and procedures adequate to avoid cross contamination and contamination by dust and other particulates in the compounding area. **D.** The pharmacy demonstrates that any equipment and surfaces involved in the compounding process is appropriately cleaned and/or sanitized before and after compounding activity as appropriate to prevent contamination.	**No new requirements.** Existing requirements were clarified and divided into multiple standards for clarity. Review the full standards manual for complete compliance requirements for each standard below. **Standard TCRX6-L: Written policies and procedures are established and implemented in regard to compounding sterile preparations in accordance with USP Chapter <797> standards, the art and science of pharmacy, and applicable laws and regulations.** **Standard TCRX6-M: Non-hazardous sterile preparations are compounded in an environment that meets requirements for the appropriate risk level as defined by USP Chapter <797>, state board of pharmacy regulations, and standards of good practice.** **Standard TCRX6-N: Written policies and procedures are established and implemented in regard to how hazardous sterile preparations are compounded in an environment that meets requirements for the appropriate risk level as defined by USP Chapter <797>, state board of pharmacy regulations, and standards of good practice.**
E. The pharmacy has SOPs for cleaning and maintaining equipment and for the establishment of cleaning and maintenance schedules. **F.** The pharmacy documents that it performs periodic environmental tests of the aseptic environment according to current USP <797> standards.	**Standard TCRX6-O: Written policies and procedures are established and implemented for cleaning, disinfecting and monitoring the controlled air environment(s).**
G. The pharmacy documents that it monitors and tests sterile compounded preparations for sterility, bacterial endotoxins, pyrogenicity, and strength of ingredients potency according to current USP <797> standards.	**Standard TCRX5-G: Written policies and procedures are established and implemented regarding continuous quality control for finished preparations.** **Standard TCRX6-R: Written policies and procedures are established and implemented to assure preparations adhere to requirements for sterility and endotoxin limits.**

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Legacy PCAB Standard	Revised PCAB Standard
Standard 4.10 General: The pharmacy maintains standard operating procedures related to the acquisition, storage, usage, and proper destruction of drug substances and drug products that are used as components in the compounding of preparations. Drug substances and products used to compound meet official compendial standards, if any, including current USP-NF standards, and are accompanied by certificate of analysis that documents the strength, quality, purity, and integrity of the drug substance. **Compliance Indicators** **A.** The pharmacy has SOPs governing the acquisition of all chemicals, drug products, and components from reliable sources. **B.** The SOPs provide that certificates of analysis be retained electronically or in hard copy by the pharmacy for a period of not less than two years. **C.** The SOPs provide that certificates of analysis be reviewed by properly trained personnel prior to the release drug substances of chemicals for use in compounding. **D.** The pharmacy documents that it uses appropriate suppliers as the source of all bulk chemical ingredients, inactive ingredients or excipients, and other components used in compounding. The pharmacy obtains the following information from appropriate suppliers: 1. FDA registered and inspected, if applicable; 2. Documentation indicating compliance with FDA-current Good Manufacturing Practices 3. Proof of licensure in good standing with applicable state and/or federal regulatory bodies. 4. Ability to provide ready access to Certificates of Analysis (COA) and Material Safety Data Sheets (MSDS) with all bulk chemicals. **E.** The pharmacy demonstrates that the SOPs address criteria for identifying and using suppliers for devices, containers, and closures used in compounding including complying with any applicable compendial standards, if applicable. **F.** The SOPs address contingency plans should an active pharmaceutical ingredient, inactive ingredient, excipient, or other component used in compounding become unavailable from any supplier meeting the above criteria. The SOPs set forth an adequate mechanism directing the Pharmacist in charge to employ professional judgment in receiving, storing, and using such components from another quality source.	**Note:** The revised standard incorporates ingredient requirements added by H.R.3204, the Drug Quality and Security Act. **Standard TCRX6-F: Written policies and procedures are established and implemented for compounding preparations that outline the selection of ingredients and are in compliance with applicable law, regulations and standards of good practice.** **Interpretation:** Written policies and procedures are established for compounding preparations that outline the selection of ingredients in a manner that is compliant with applicable laws, regulations, and standards of good practice, which include but are not limited to: • A process for documenting that suppliers for bulk chemicals are FDA registered, licensed in good standing and are able to provide Certificates of Analysis (COAs) and Safety Data Sheets (SDSs) • Criteria for acceptance or rejection of components based upon COA review and other criteria • A process for incorporating pertinent COA data into MFRs and for the retention of COAs • A process for ensuring that the pharmacy does not compound for human patients with medications included on the FDAs "List of Drug Products That Have Been Withdrawn or Removed from the Market for Reasons of Safety or Effectiveness," or the FDA's "Demonstrable Difficulties for Compounding" list. • Bulk substances comply with the standards of an applicable USP or National Formulary (NF) monograph, if one exists • If a monograph does not exist, the drug substance(s) in compounded medications for human patients must be a component of an FDA-approved human drug product • If a monograph does not exist and the drug substance in compounded medications for human patients is not a component of an FDA-approved human drug product, it must appear on a list of bulk drug substances for use in compounding developed by the FDA • Official compounded preparations are prepared from ingredients that meet requirements of the compendial monograph for those individual ingredients for which monographs are provided • For non-sterile preparations, ensuring that components that do not have expiration dates assigned by the supplier are labeled with the date of receipt and are assigned a conservative expiration date based on stability data and not to exceed three years from the date of receipt

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G. The pharmacy documents that it uses high-quality active pharmaceutical ingredients (APIs) for use in compounding that: **1.** Meets current USP/NF grades substances. If not available, then the use of other high-quality sources, such as: i. Analytical reagent (AR), ii. Certified American Chemical Society (ACS), or iii. Food Chemicals Codex (FCC) grade, are permitted as sources of active ingredients when appropriate. iv. Dietary and nutritional supplements that are "Generally Recognized As Safe" **2.** Meets other compendial standards, or **3.** Are components of products that have been approved by FDA or grand-fathered under the Food, Drug & Cosmetic Act of 1938 (FDCA). **H.** The pharmacy complies with the FDA's "List of Drug Products That Have Been Withdrawn or Removed from the Market for Reasons of Safety or Effectiveness," subject to the exceptions provided in such list. Written SOPs exist to safeguard against the use of such components in compounded preparations for human patients. **I.** The pharmacy demonstrates that it has a designated area for the receiving and inspection of chemicals, devices, containers, closures, and other components or supplies used in the compounding operation. **J.** The pharmacy has SOPs that assure Material Safety Data Sheets (MSDS) are properly maintained and readily retrievable. **K.** The pharmacy has SOPs that outline the criteria for acceptance or refusal of components. **L.** The pharmacy demonstrates that upon receipt of a chemical or drug substance, it is quarantined until the Certificate of Analysis (COA) information is verified by properly trained compounding personnel and the MSDS information is assessed for review, as necessary.	• For sterile preparations, the date of receipt for bulk substances and excipients will be clearly and indelibly marked on each package of ingredient, packages of ingredients that lack a supplier's expiration date cannot be used after one year unless either appropriate inspection or testing indicates that the ingredient has retained its purity and quality
Standard 4.20 Handling, Storage, and Disposal: The pharmacy safely handles, stores, and disposes of all chemicals, drug products, and components according to compendial and other applicable requirements. Appropriate storage of chemicals, components, and completed compounded preparations shall be designed to maintain their strength, quality, purity, integrity, and, where applicable, sterility.	**Standard TCRX6-C: Written policies and procedures are established and implemented relating to the storage of pharmaceuticals, components (including active pharmaceutical ingredients, excipients, ingredients, and devices) and compounded preparations.**

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Legacy PCAB Standard	Revised PCAB Standard
Standard 5.00 Formulation Record and Compounding Record: The pharmacy uses a Formulation Record (FR) that assures the strength, quality, purity, integrity, and, where applicable, sterility of the compounded preparation. The pharmacy uses a Compounding Record (CR) for assuring that the procedures employed to prepare compounded preparations are consistent and reproducible. Compounding activities and processes shall be subject to verification of preparations for strength, quality, purity, integrity, and where applicable, sterility that meet or exceed compendial standards.	Standard TCRX6-G: Written policies and procedures are established and implemented that outline the contents of the Master Formulation Record for each compounded preparation. Standard TCRX6-H: Written policies and procedures are established and implemented that outline the contents of the compounding record for each preparation.
Standard 6.10 Beyond-Use Date: The pharmacy determines and assigns beyond-use dates to all its compounded preparations.	Standard TCRX6-P: Written policies and procedures are established and implemented in regard to assigning each non-sterile preparation a Beyond-Use Date (BUD) to assure that the preparation retains its strength, purity, and quality until the labeled BUD date. Standard TCRX6-Q: Written policies and procedures are established and implemented in regard to assigning each sterile preparation a Beyond-Use Date (BUD) to assure that the preparation retains its strength, purity, and quality until the labeled BUD date.
Standard 6.20 Potency: Compounded preparations meet established and/or compendial requirements of strength, quality, purity, potency, and stability throughout the period for intended use when stored as labeled.	Standard TCRX5-G: Written policies and procedures are established and implemented regarding continuous quality control for finished preparations.
Standard 6.30 Sterility: Compounded preparations adhere to established and/or compendial requirements of sterility and bacterial endotoxin limits, throughout the period for intended use when stored as labeled.	Standard TCRX6-R: Written policies and procedures are established and implemented to assure preparations adhere to requirements for sterility and endotoxin limits.

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Legacy PCAB Standard	Revised PCAB Standard
Standard 7.10 Packaging, Labeling, and Delivery for Administration and Dispensing: The pharmacy adheres to state, federal, and compendial requirements related to packaging, labeling, dispensing, and delivery for administration of compounded preparations.	**New Requirements:** **Standard TCRX4-B: Written policies and procedures are established and implemented that address the timeliness of shipping, shipping errors, turnaround time, and lost shipments.** **Interpretation:** Written policies and procedures include, but are not limited to: • Timeliness of shipping to ensure the client/patient receives medication prior to the administration date • Ability to track the preparations after they leave the organization • Notifying the client/patient if the shipment will be delayed • Processes in place to ensure the client/patient has a continuous supply of medication if shipment is delayed or lost Personnel implement the policies and procedures for the process of tracking shipments. **Standard TCRX6-D: The organization uses delivery containers that assure pharmaceuticals are maintained under appropriate conditions of sanitation, light, and temperature in the course of deliveries.**
Standard 7.20 Internal and External Recalls: The pharmacy has procedures for the appropriate and timely recall of dispensed compounded preparations when subsequent testing or other information demonstrates that the compounded preparation does not meet its declared strength, quality, purity, and, where appropriate, sterility and bacterial endotoxin limit.	**Standard TCRX5-E: Written policies and procedures are established and implemented by the organization to identify, monitor, report, investigate, and document all adverse events, incidents, accidents, variances, or unusual occurrences that involve clients/patients who receive compounded preparations.** **New Requirement:** There are written policies and procedures for the organization to comply with the FDA and state boards of pharmacy to facilitate any recall notices submitted by the manufacturer, if applicable. **Standard TCRX6-B: Written policies and procedures are established and implemented for preparation and/or component recall.**
Standard 7.30 Labeling: The pharmacy labels completed compounded preparations according to the PCAB® Labeling Guidelines.	**Standard TCRX6-U: Written policies and procedures are established and implemented to assure that compounded preparations are labeled in accordance with applicable laws and regulations, USP standards, and standards of good practice.**

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Standard 8.10 Prescriber Communication: The pharmacy communicates with prescribers about preparations that are compounded for their patients. **Compliance Indicators:** **A.** The pharmacy has SOPs that address: **1.** A method to assure that, if it is not unmistakably evident or not indicated on the original prescription or order that the medication is to be compounded, it is confirmed with the prescriber that the preparation will be compounded. **2.** A method to disclose to prescribers all ingredients and methods of compounding as may be necessary in the event of an adverse event or possible untoward reaction. **B.** The pharmacy demonstrates that such communications with prescribers occur regularly.	**No equivalent standard.** The requirements of this standard are met by compliance with other revised PCAB standards.
Standard 8.20 Patient Education: A pharmacy complies with state and federal patient education and counseling requirements. **Compliance Indicators** **A.** The pharmacy's SOPs include a responsibility to provide education and counseling to patients and/or caregivers. **B.** The pharmacy demonstrates that it offers and provides to patients and/or caregivers education and consultation. **C.** The pharmacy has suitable written materials to provide the patient or caregiver with information on the appropriate use of compounded preparations, if applicable. **D.** The pharmacy demonstrates that prospective drug reviews are conducted prior to dispensing compounded preparations.	**Standard TCRX4-A: A Registered Pharmacist reviews ail client/patient medications and consults with other health care professionals caring for the client/patient, including the physician, as applicable. All Omnibus Budget Reconciliation Act (OBRA) counseling is completed as specified by law.** **Note:** Clarifies counseling, education, and monitoring requirements including: **Interpretation:** The pharmacy obtains the age, gender, allergies, species (for veterinary patients), medical conditions and pertinent information that may affect drug utilization. Prior to dispensing compounded medications a Pharmacist reviews all prescription and non-prescription medications that a client/patient is currently taking. A medication profile is established at the start of therapy. This profile is updated whenever there are changes in the client's/patient's medication therapy or as designated by the pharmacy policies and procedures. A Registered Pharmacist is specifically responsible for recognizing the following as they pertain to compounded medications dispensed by the pharmacy: • Side effects • Toxic effects • Allergic reactions • Desired effects • Unusual and unexpected effects • Actual or potential drug interactions • Appropriateness of the drug for the client's/patient's diagnosis • Appropriateness of the dose • Changes in the client's/patient's condition that contraindicate continued use of the drug

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	The Pharmacist, in conjunction with other healthcare professionals, is able to anticipate those effects that may rapidly endanger a client's/patient's life or wellbeing and instructs the client/patient in the prescribed regimen. **Standard TCRX6-S: The organization ensures that pharmaceuticals are stored under appropriate conditions of sanitation, light, and temperature in the client's/patient's home.** **Interpretation:** Pharmaceuticals dispensed to the client/patient are clearly labeled with the appropriate storage conditions requirements. The organization educates the client/patient on the appropriate conditions for the storage of pharmaceuticals in the home environment. When necessary, the Pharmacist intervenes to ensure that appropriate conditions are achieved or maintained.
Standard 9.10 Quality Assurance (QA) Activities: The pharmacy has in place and adheres to a written quality assurance plan that, at a minimum on an annual basis, verifies, monitors, and reviews the adequacy of the compounding process. Quality assurance activities assure that compounded preparations meet criteria for identity, strength, quality, purity, and, where appropriate, sterility and bacterial endotoxin limit.	**Note:** The revised standards establish a performance monitoring and improvement program. See Standards TCRX5-A through TCRX5-L below.
Standard 9.20 Quality Control (QC) Activities: The pharmacy has in place and adheres to a written quality control plan. **Compliance Indicators** **A.** The pharmacy maintains SOPs related to its QC activities and has designated personnel responsible for QC activities. **B.** The pharmacy demonstrates that its QC plan references how compounded preparations meet current USP standards for strength, quality, purity, integrity, and, where applicable, sterility and bacterial endotoxin limit.	**Standard TCRX5-G: Written policies and procedures are established and implemented regarding continuous quality control for finished preparations.** Review the full standards manual for complete compliance requirements for this standard.
Standard 9.30 Quality Related Events (QREs): The pharmacy has in place and adheres to written SOPs for documenting and handling QREs.	**Standard TCRX5-E: Written policies and procedures are established and implemented by the organization to identify, monitor, report, investigate and document all adverse events, incidents, accidents, variances, or unusual occurrences that involve clients/patients who receive compounded preparations.**

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Legacy PCAB Standard	Revised PCAB Standard
Standard 9.40 Quality Improvement (QI) Activities: The pharmacy has in place and adheres to a quality improvement plan that is designed to: **A.** Objectively and systematically collect data about the operations of the compounding process; **B.** Evaluate this data and its effect on patient care; **C.** Propose and select resolutions to identified problems and **D.** Collect data on whether the selected resolution(s) has/ have the intended effect. Quality improvements are incorporated into SOPs, employees are trained in their use, and improvements are communicated to patients and prescribers, where appropriate. The pharmacy uses data and findings from its QA, QC, and QRE monitoring and reporting to identify quality improvement priorities. **Compliance Indicators** **A.** The pharmacy maintains SOPs related to its QI activities.	**Standard TCRX5-A: The organization develops, implements, and maintains an effective, ongoing, organization-wide Performance Improvement (PI) Program.** **Interpretation:** Each organization develops a program that is specific to its needs. The methods used by the organization for reviewing data include, but are not limited to: • Current documentation (e.g., review of client/patient records, incident reports, and complaints) • Direct observation • Interviews with personnel **Note:** Review Standards TCRX5-B through TCRX5-L for additional details regarding these requirements: The data collected by the organization for self-assessment includes, but is not limited to: • Adverse events • Client/patient complaints • Client/patient records • At least one important aspect related to the service provided • Ongoing monitoring of processes that involve risks including infections and communicable diseases **Standard TCRX5-B: The organization ensures the implementation of an organizational-wide Performance Improvement (PI) Plan by the designation of a person responsible for coordinating PI activities.** **New requirement:** **Standard TCRX5-C: There is evidence of personnel involvement in the Performance Improvement (PI) process**. **Interpretation:** Personnel receive training related to PI activities and their involvement. Training includes, but is not limited to: * The purpose of PI activities * Person responsible for coordinating PI activities * Individual's role in PI * PI outcomes resulting from previous activities Personnel are involved in the evaluation process through carrying out PI activities, evaluating findings, recommending action plans, and/ or receiving reports of findings.

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B. The pharmacy demonstrates that its QI activities include the collection of QA, QC, QRE and other data to identify priorities for improvement.	**New Requirements:** The revised standards specify a specific format/methodology for the pharmacy's Performance Improvement (PI) activities. This format and methodology applies to the requirements of TCRX5-F, TCRX5-H, TCRX5-I, and TCRX5-J, and other PI activities/studies the pharmacy implements. **Standard TCRX5-D: Each performance improvement (PI) activity or study contains the required items.** **Interpretation:** Each PI activity/study includes the following items: • A description of indicators to be monitored/activities to be conducted • Frequency of activities • Designation of who is responsible for conducting the activities • Methods of data collection • Acceptable limits for findings • Designation of who will receive the reports • Plans to re-evaluate if findings fail to meet acceptable limits • Any other activities required under state or federal laws or regulations **Standard TCRX5-F: Performance Improvement (PI) activities include an assessment of processes that involve risks, including infections and communicable diseases.** **Standard TCRX5-H: Performance Improvement (PI) activities include ongoing monitoring of at least one important aspect related to the non-sterile compounding process.** **Standard TCRX5-I: Performance Improvement (PI) activities include ongoing monitoring of at least one important aspect related to the sterile compounding process.** **Standard TCRX5-J: Performance Improvement (PI) activities include the ongoing monitoring of client/patient complaints/ grievances.** **Standard TCRX5-K: There is a written plan of correction (POC) developed in response to any Performance Improvement (PI) findings that do not meet an acceptable threshold.**
C. The pharmacy provides examples of communicating QI activities to patients and prescribers, when appropriate and applicable.	Addressed by various other standards including TCRX2-A and TCRX5-E

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New Requirement	**Standard TCRX5-L: There is an annual Performance Improvement (PI) report written.** **Interpretation:** There is a comprehensive, written annual report that describes the PI activities, findings and corrective actions that relate to the service provided. In a large, multi-service organization, the report may be part of a larger document addressing all of the organization's programs. While the final report is a single document, improvement activities must be conducted at various times during the year. Data for the annual PI report may be obtained from a variety of sources and methods, such as audit reports, client/patient questionnaires, feedback from referral sources and outside survey reports.
New Requirement	**Standard TCRX6-A: Written policies and procedures are established and implemented that address the surveillance, identification, prevention, control, and investigation of infectious and communicable diseases and the compliance with regulatory standards.**
New Requirement	**Standard TCRX6-T: Written policies and procedures are established and implemented for participating in clinical research/experimental therapies and/or administering investigational drugs.**
New Requirement – Non-Sterile Annual Reporting	**Standard TCRX7-A: Organizations that are PCAB Accredited for Non-Sterile Compounding are required to provide documentation as evidence of compliance on an annual basis. This documentation is submitted two months prior to the expiration of the annual PCAB Accreditation. (This is an informational standard only for providers applying for Non-Sterile Compounding for the first time.)**
New Requirement – Sterile Annual Reporting	**Standard TCRX7-B: Organizations that are PCAB Accredited for Sterile Compounding are required to provide documentation as evidence of continued compliance on an annual basis. This documentation is submitted two months prior to the expiration of the annual PCAB Accreditation. (This is an informational standard only for providers applying for sterile compounding for the first time.)**

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Legacy PCAB Standard	Revised PCAB Standard
1.10	TCRX1-A
1.30	TCRX1-B
PCAB Terms and Conditions	TCRX1-C
9.30	TCRX2-A
2.10, 2.30	TCRX3-A
2.10, 2.30	TCRX3-B
2.10, 2.30	TCRX3-C
2.10, 2.30	TCRX3-D
2.10, 2.30	TCRX3-E
2.10, 2.30	TCRX3-F
1.10, 2.20, 2.30	TCRX3-G
2.20	TCRX3-H
2.30	TCRX3-I
2.20, 2.30	TCRX3-J
3.11	TCRX3-K
2.30, 8.10, 8.20	TCRX4-A
7.10	TCRX4-B
9.10, 9.30, 9.40	TCRX5-A

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9.20, 9.40	TCRX5-B
9.40	TCRX5-C
9.40	TCRX5-D
9.30	TCRX5-E
No equivalent PCAB standard	TCRX5-F
9.20	TCRX5-G
No equivalent PCAB standard	TCRX5-H
No equivalent PCAB standard	TCRX5-I
No equivalent PCAB standard	TCRX5-J
No equivalent PCAB standard	TCRX5-K
No equivalent PCAB standard	TCRX5-L
2.10, 2.20, 2.30	TCRX6-A
7.20	TCRX6-B
4.10	TCRX6-C
7.10	TCRX6-D
3.10, 3.30	TCRX6-E

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4.10	TCRX6-F
5.00	TCRX6-G
5.00	TCRX6-H
3.20	TCRX6-I
3.10, 3.20	TCRX6-J
3.20	TCRX6-K
3.30	TCRX6-L
3.30	TCRX6-M
3.10, 3.30	TCRX6-N
3.30	TCRX6-O
6.10, 6.20	TCRX6-P
6.10, 6.20	TCRX6-Q
6.30	TCRX6-R
8.20	TCRX6-S
No equivalent PCAB standard	TCRX6-T
7.30	TCRX6-U
No equivalent PCAB standard	TCRX7-A
No equivalent PCAB standard	TCRX7-B

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