November 1, 2015

RECEIVED
NOV 06 2015
IOWA BOARD OF PHARMACY

ACHC | PCAB PHARMACY COMPOUNDING ACCREDITATION BOARD

Mr. Andrew Funk
Iowa Board of Pharmacy

Dear Mr. Funk,

Re: Compounded Drugs – What tools can a state utilize to preserve access while at the same time fulfilling the mission of protecting public safety?

Many Boards of Pharmacy are struggling with the challenge of protecting patient safety while still providing critical access to compounded medications, and are attempting to implement the necessary parameters/restrictions to ensure that an event similar to the 2012 NECC meningitis outbreak never happens again. Unfortunately, despite good intentions, some of the requirements being considered to protect the public and compounding pharmacy employees are inadequate and do not produce the desired result.

I am José Domingos, CEO for Accreditation Commission for Health Care (ACHC). We offer the most comprehensive compounding accreditation program in the industry (PCAB) and have surveyed more than 400 compounding pharmacies. Most pharmacies that pursue PCAB Accreditation believe they are doing things correctly and want to achieve accreditation to differentiate themselves from their peers. Unfortunately, more often than not, what we find is that they don't know what they don't know. They want to do the right thing and are committed to becoming a better provider, but too many of them are compounding in a way that continues to put their patients and employees at risk. PCAB Accreditation in combination with their commitment to continuous compliance helps them significantly reduce their potential of ever experiencing an NECC-type event.

There is currently no other accreditation program in the industry that integrates USP requirements to the level that we do and that requires a plan (and evidence) of correction to abate the findings discovered during our surveys. Some Boards of Pharmacy are requiring either NABP's VPP inspection program or ACHC's Inspection Services (AIS) program in an attempt to improve patient safety. Unfortunately, although both of these programs serve a purpose, they only offer a "snapshot in time" of whether a pharmacy does or does not meet a certain requirement. These services do not make them a better pharmacy as they do not compel the pharmacy to address the root causes of their deficiencies, nor do these programs require the annual demonstration of continuous compliance required by PCAB. It has long been accepted by students of Quality Improvement methods across all industries that "Quality By Inspection" is an inefficient and costly practice compared with "Quality By Design." Only PCAB Accreditation requires a pharmacy to incorporate Quality Improvement planning into its everyday operations.

We know that Boards of Pharmacy are not simply looking to check a box but are instead looking for solutions that make a real difference. Choosing an inspection program, whether it is NABP's VPP or ACHC's AIS program will produce an episodic hurdle that simply needs to be overcome. It does not produce the comprehensive, substantive impact Boards of Pharmacy desire. Only PCAB Accreditation will provide that result.

We would like to provide more information on how PCAB Accreditation can be the difference and would appreciate the opportunity to present materials at an upcoming board meeting. Minimally, your board will be better informed in order to make decisions that best suit your goals. Please contact me toll free at 855-937-2242 to choose a time that is mutually acceptable, given that we are aligned in our goal to improve both patient and pharmacy employee safety. Thank you for your consideration.

Sincerely,

José Domingos
CEO
Accreditation Commission for Health Care

FOR PROVIDERS.
BY PROVIDERS.™

COMPOUNDING COMPLIANCE

ACHC Inspection Services (AIS) Inspection

Pharmacy Compounding Accreditation Board (PCAB) Accreditation

PHARMACY COMPOUNDING ACCREDITATION BOARD

ACCREDITATION COMMISSION *for* HEALTH CARE

COMPOUNDING COMPLIANCE

- Compounding pharmacies are a unique subset of the industry
- Estimated that 1-3% of prescriptions in the US are compounded[1]
- Inconsistencies create challenges for regulatory bodies
  - Pharmacies
    - Rapidly evolving products and services , facilities, equipment
  - State boards of pharmacy
    - State-to-state variance, complicates interstate delivery
  - Patients and Prescribers
    - Market drivers create unique subsets of practice

1. IACPRX.org (December, 2015)

COMPOUNDING COMPLIANCE

Involvement of multiple agencies creates confusion

- State Boards of Pharmacy
- Federal Agencies
  - Food and Drug Administration (FDA)
    - DQSA – 503A vs. 503B?
    - Warning letters and Form 483 observations
  - Drug Enforcement Agency (DEA)
  - Centers for Disease Control and Prevention (CDC)
  - Occupational Safety and Health Administration (OSHA)
- USP

COMPOUNDING COMPLIANCE

- U.S. Pharmacopeial (USP) practice guidelines
  - Non-governmental standard-setting organization, often cited by regulators
  - Considered by experts to be the minimum standard by which a pharmacy should operate
  - Boards of pharmacy may require full or partial compliance
  - USP<795> - non-sterile compounding
  - USP<797> - sterile compounding
  - Associated USP Chapters: <85>, <71>, <1163>

- HOWEVER, USP is non-regulatory

COMPOUNDING COMPLIANCE

- Accreditation is one solution that pharmacies have chosen to demonstrate compliance
  - PCAB – The industry's most comprehensive compliance solution
- Inspection services
  - ACHC Inspection Services
  - National Association of Boards of Pharmacy (NABP) – Verified Pharmacy Program

ACHC PHARMACY SURVEYORS/ INSPECTORS

- Requirements for compounding pharmacy Surveyors/Inspectors include
  - Registered Pharmacist with an active professional license
  - Minimum of five years of experience in sterile and/or non-sterile pharmacy compounding with at least two years in a management role
  - State-specific training conducted as required
  - A minimum of two precepted training surveys and ongoing education
- ACHC has a total of 22 trained and qualified pharmacy Surveyors, including PCAB Surveyors
  - Examples of the experience held by ACHC Surveyors include
    - Appointed to the USP expert panel for sterile compounding
    - 29 years of sterile compounding experience
    - Conducted more than 250 surveys of pharmacies compounding sterile preparations

PROGRAM COMPARISON

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	ACHC		
Features	**PCAB**	**AIS**	**VPP[1]**
Safety			
Review of USP <795>	✓	✓	✓
Review of USP <797>	✓	✓	✓
Additional Requirements	Does the pharmacy's Performance Improvement (PI) Plan meet key criteria, including (but not limited to): ▪ How the plan will be conducted ▪ Responsible individuals ▪ Which tasks will be reviewed ▪ Outcome goals ▪ Root cause analysis ▪ Review of patient complaints and adverse events ▪ PI outcomes	Does the pharmacy have a PI Plan? Yes/No	Does the pharmacy have a PI Plan? Yes/No
Pharmacist Surveyors	✓	✓	
Annual Verification of compliance	✓		
Administrative			
Customized to state requirements	✓	✓	✓
Prompt access to findings[2]	✓	✓	✓
Survey cycle[3]	3 years	State dependent	State dependent
Base price	$8,500	$2,995	$3,000
Post-survey correction	Pharmacy submits Plan of Correction (POC)[4]	State dependent	Pharmacy provides written response
Payor Recognition	Many payors recognize PCAB Accreditation as benchmark of quality		
Prescriber Recognition	Many physicians refer patients to PCAB Accredited pharmacies		

1. VPP information gathered from NABP.org as of 10/2015
2. For PCAB, findings are available with pharmacy's permission or regulatory requirement
3. Inspection requirements typically follow a 2-year cycle
4. Plan of Correction requirements are detailed on Process Comparison Grid

PHARMACY COMPOUNDING ACCREDITATION BOARD

PROCESS COMPARISON

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	PCAB	AIS
Type	Accreditation	Inspection
	PCAB surveys provide a consultative review of compliance with PCAB standards, referencing USP <795>/<797>. Surveyor documents deficiencies along with corrective action required.	AIS Inspections provide a data collection service built on requirements for USP <795>/<797>. Findings are recorded in a YES/NO format.
Review Process	An independent reviewer analyzes survey findings in order to provide consistency and appropriateness. A review committee determines the Accreditation Decision.	Minimal review is required. The findings are submitted to the State Board or appropriate agency. AIS provides a recommendation (not decision) based on state preferences.
	The pharmacy formally responds to deficiencies with Plan of Correction (POC) and appropriate evidence. This process allows for dialogue between PCAB and the pharmacy to mitigate deficiencies.	The State Board receives the completed inspection form and determines outcome/licensing decision.
	The POC defines what the pharmacy is going to do, when it will be done, and how it will be done. Select evidence is required to complete the process. All findings must be adequately addressed prior to approving POC. The POC helps pharmacies to eliminate gaps between their practice and the actual requirement.	
	A Review committee analyzes the submitted Plan of Correction and evidence and provides a written response to the pharmacy.	
	A decision is made whether to require additional evidence, request evidence of continual compliance, or follow up with a re-survey.	
Follow-Up	Annual verification of compliance	N/A
	The Pharmacy must demonstrate continuous compliance through submission of documentation including: Equipment training/competency, New personnel training, ongoing personnel competency, sterility and endotoxin summary log (sterile only), equipment calibration and certification, quality control procedures, sampling of formulation records, overview of performance improvement.	
	The annual verification of compliance demonstrates continued compliance in between on-site surveys.	

PHARMACY COMPOUNDING ACCREDITATION BOARD

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 beginning once deficiencies are addressed.

***For Home Health, Hospice, and Behavioral Health providers, all requirements must be met for full accreditation.**

SAMPLE SOF

Survey Report for Survey on 02/03/2015
Services: CFNS

ACHC

Deficiency Category - Interviews/Observations			
Standard		**Comments**	**Deficient**
TCRX5-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**	**Deficient**
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.**	The pharmacy provided evidence of a recently developed annual competency assessment for staff. The competency assessment was an observational audit that was performed during the compounding of a topical preparation. The assessment did not include a potency test. The assessment was for only one type of dosage form and the pharmacy also prepares suppositories and capsules. Initial competency assessments, at the time of hire and before compounding, were performed and not documented. It is noted that the pharmacy provided evidence of a read and understand document for each of the P&Ps. It was discussed during the survey, that the read and understand is not a documented competency assessment; however, the P&P could be used as an audit tool for future competency assessments along with the compounding record and potency test. Action Required: The pharmacy's plan of correction needs needs to include developing an audit tool that	X

AIS | PCAB PHARMACY COMPOUNDING ACCREDITATION BOARD

PLAN OF CORRECTION (POC)

FOR PROVIDERS. BY PROVIDERS.

Organization: Company ID: Application ID:

Address:

Services Reviewed: Date of Survey: Surveyor:

INSTRUCTIONS

- Standards that require supportive evidence of correction are indicated in the last section of summary of findings titled "Quality & Supplier with Evidence Required on POC"
- These standards are already listed under the "Standard" column on the following pages and should be filled out accordingly. There is a sample below.
- For corrective action measures that require chart audits, please be sure to include the frequency of the audit.
- Contact your Accreditation Advisor for any questions or if you need help filling out your POC.

SAMPLE

Below is a sample on how to correctly fill out your POC.

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

ACHC Internal Use Only

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	Comments
DRX5-1A	Added a place to the intake form to document the emergency contact name and number. Re-educated employees to obtain an emergency contact number and diagnosis for all patients.	18-Jan-15	Office Manager	Audit a minimum of 10% of new patient files on a quarterly basis to determine if a diagnosis and emergency contact number have been documented.	ACHC INTERNAL USE ONLY. LEAVE THIS AREA BLANK.	
DRX6-3A	Customer service manager has started tracking the number of complaints received each month and will monitor them to see if a problem develops. Results will be reported to the performance improvement committee on a quarterly basis.	14-Jan-15	Customer Service Manager	100% of client/patient complaints will be tracked, investigated, and summarized. A report will be submitted quarterly to the performance improvement committee for review and monitoring of compliance with policies and procedures.		

ACCREDITATION

Benefits to public

- Improved safety and quality
  - Consistent practices result in improved safety, efficiency, and quality of care
- Risk aversion
  - ACHC provides an added measure of assurance for patient and employee safety in addition to reducing pharmacy risks
- Continuity of service
  - Accreditation facilitates a standardized level of service that includes sound procedures, documentation, and training to ensure consistent performance

ACCREDITATION

Benefits to regulatory bodies

- Third party solution
  - Independent 3rd party verifies compliance with industry standards as well as ensure continuous quality improvement
- Cost savings
  - Provider-funded service
- Resource management
  - The accreditation organization maintains the infrastructure to conduct accreditation surveys
- Reliability
  - Accreditation utilizes the extensive experience of industry Surveyors to conduct consistent, thorough surveys
- Transparency
  - Accreditation findings can be shared with key stakeholders

RECOMMENDATION

- Recognize PCAB Accreditation
  - PCAB Accreditation exceeds inspection requirements
  - Established value and proven track record
  - Nationally recognized by third-party payors
  - Prescriber recognition of PCAB
  - Serves as an extension of State Inspectors

ADDITIONAL ACHC INFORMATION

ACCREDITATION COMMISSION *for* HEALTH CARE

ABOUT ACHC

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.

- Nationally recognized accreditation organization with 29 years of experience
- CMS Deeming Authority for Home Health, Hospice, and DMEPOS
- Recognition by major third-party payors
- Approved to perform state licensure surveys
- First accreditation organization with a Quality Management System certified to ISO 9001:2008

ACHC MISSION AND VALUES

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.

Values:

1. Committed to successful collaborative relationships
2. Flexibility without compromising quality
3. Every employee is accountable for their contribution to providing the best possible experience
4. We will conduct ourselves in an ethical manner in everything we do

EXTENSION OF THE EXPERIENCE

- ACHC is committed to providing value to organizations through relevant standards that set quality benchmarks, identify best practices, and promote continuous quality improvement
- Organizations, in turn, comply with these standards, validating their commitment to quality and accountability
- Downstream, providers have the required knowledge and necessary tools to provide the best possible care/service
- The patients benefit

CUSTOMER SATISFACTION

ACHC is committed to providing the best possible **experience.**

99%

of our customers regard their experience with ACHC as positive.

"ACHC was the only organization that made it a positive learning experience."

-DMEPOS PROVIDER, RALEIGH, NC

98%

of our customers would recommend ACHC.

"Our Accreditation Advisor really takes care of us!"

- HOME HEALTH AGENCY, ENGLEWOOD, CO

Customer Satisfaction Survey data gathered from 7/2015-present.

ACHC PROGRAMS & SERVICES

HOME HEALTH

BHHC—Psychiatric/Behavioral Health Home Care
HHA—Home Health Aide
SW—Social Work
OT—Occupational Therapy
PT—Physical Therapy
SN—Skilled Nursing
ST—Speech Therapy

HOSPICE

HIC—Hospice Inpatient Care
HSP—Hospice Care

PRIVATE DUTY

PDA—Private Duty Aide
PDC—Private Duty Companion/Homemaker
PDIN—Private Duty Infusion Nursing
PDN—Private Duty Nursing
PDOT—Private Duty Occupational Therapy
PDPT—Private Duty Physical Therapy
PDST—Private Duty Speech Therapy
PDSW—Private Duty Social Work

PHARMACY

AIC—Ambulatory Infusion Center
IRN—Infusion Nursing
IRX—Infusion Pharmacy
SRX—Specialty Pharmacy
LTC—Long Term Care Pharmacy
PCAB Accreditation
CFNS—Non-Sterile Compounding (Ref. USP <795>)
CFST—Sterile Compounding (Ref. USP <797>)
AIS—ACHC Inspection Services

DMEPOS

CR—Community Retail
CRCS—Clinical Respiratory Care Services
Fitter—Fitter
HME—Home/Durable Medical Equipment
MSP—Medical Supply Provider
RTS—Complex Rehabilitation and Assistive Technology Supplier

SLEEP

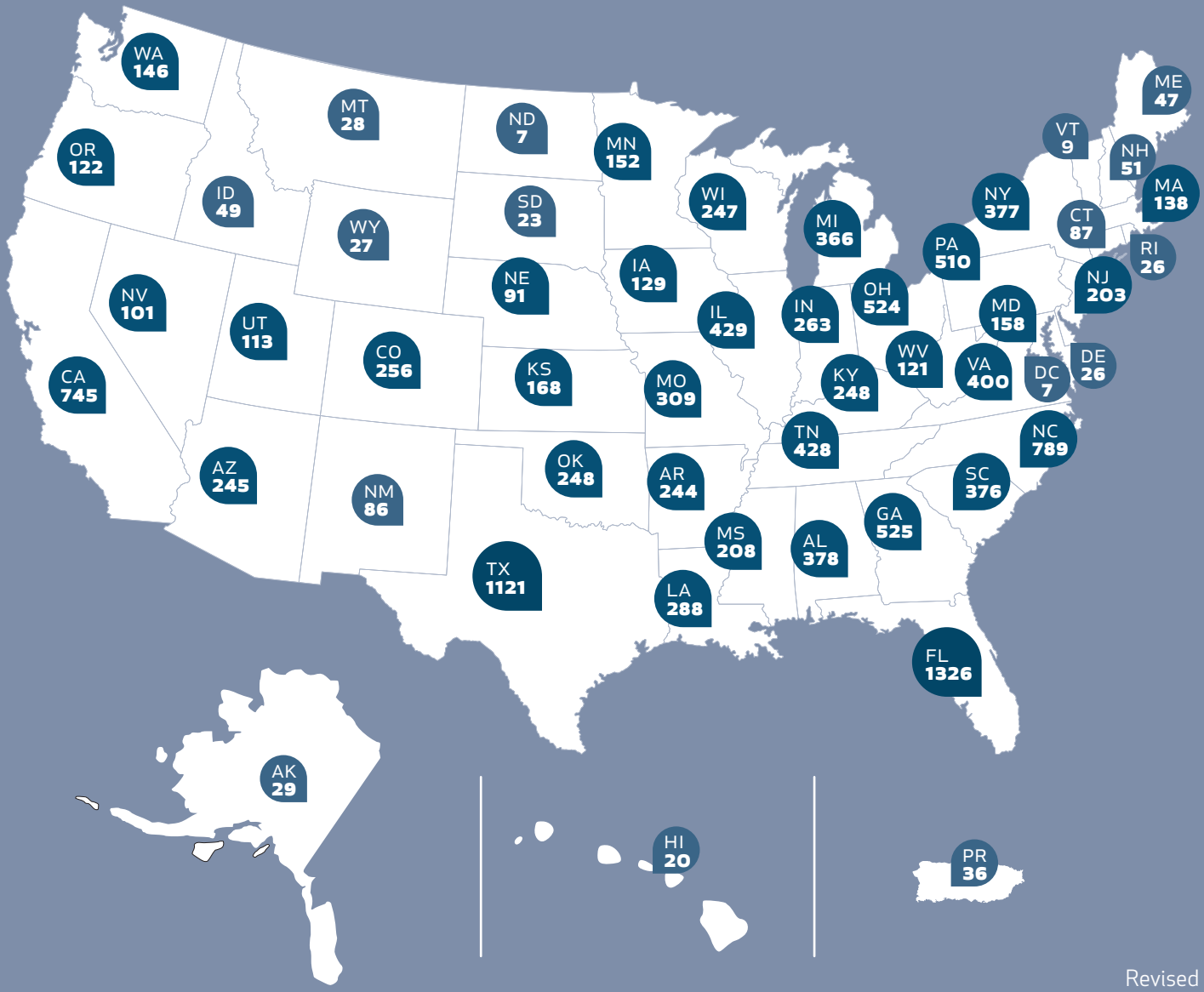
SLC—Sleep Lab/Center
HST—Home Sleep Testing

BEHAVIORAL HEALTH

ACTT—Assertive Community Treatment Team
ARS—Assessment and Referral Services
CMGT—Case Management
CS—Community Support
DTX—Day Treatment
IIH—Intensive In-Home
IOTX—Intensive Outpatient Treatment
OTX—Outpatient Treatment
PHS—Partial Hospitalization Services
PSR—Psychosocial Rehabilitation
PSS—Personal Support Services
PVS—Prevention Services
RTX—Residential Treatment
SES—Supported Employment Services
SGL—Supervised Group Living
Pending release*
BHH—Behavioral Health Home
CRS—Crisis Response Services
FCS—Foster Care Services
ICS—Integrated Care Services
RCS—Respite Care Services

*Contact ACHC for more information.

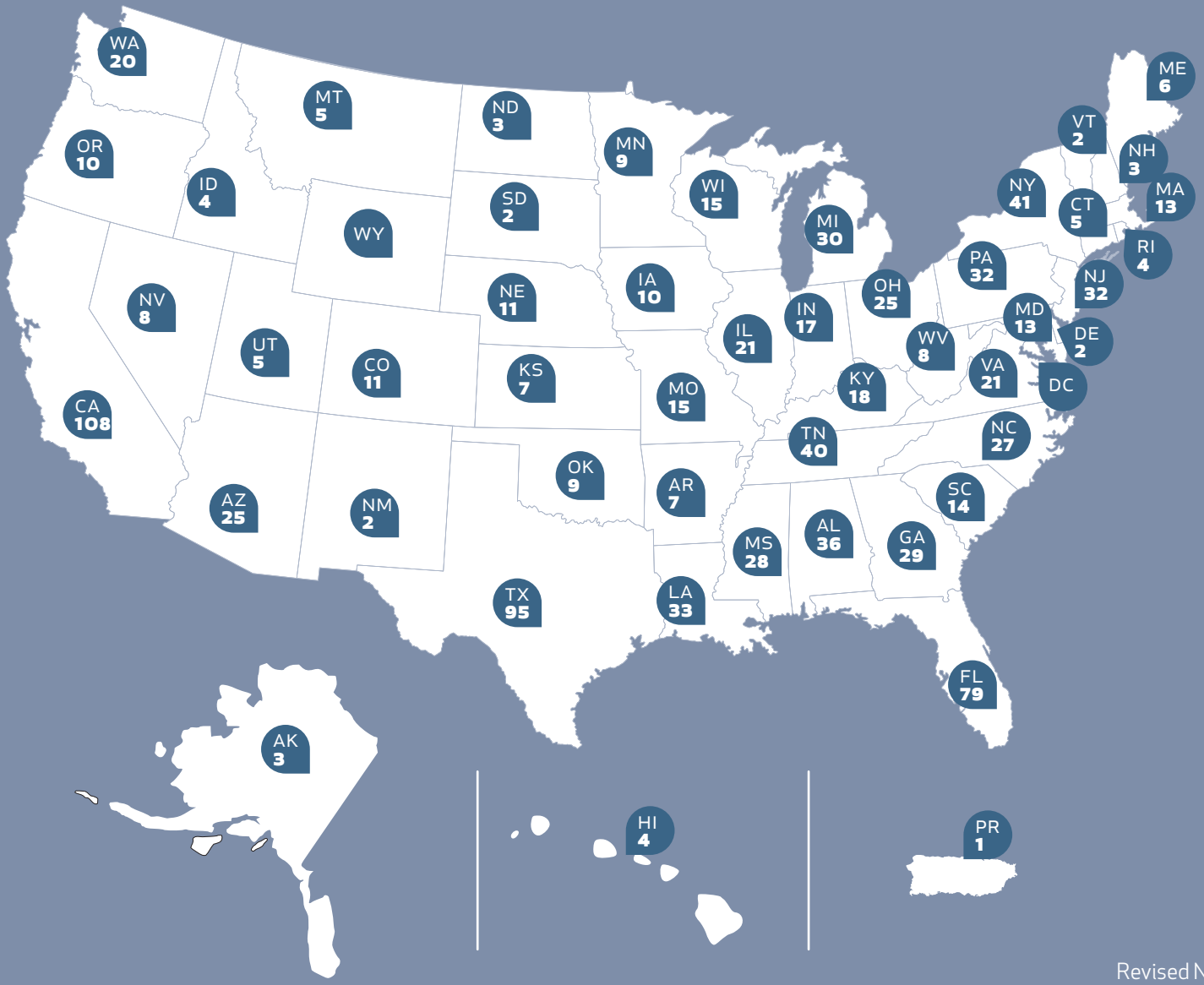
ACHC ACCREDITED LOCATIONS BY STATE



Total: 13,051

Revised November, 2015

PHARMACY ACCREDITED LOCATIONS BY STATE



Total: 969

Revised November, 2015

THANK YOU

Accreditation Commission for Health Care
139 Weston Oaks Ct., Cary, NC 27513

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ACHC

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BY PROVIDERS.™

PHARMACY

COMPOUNDING COMPLIANCE

ACHC INSPECTION SERVICES (AIS) PCAB ACCREDITATION

Iowa Board of Pharmacy

AIS
ACHC INSPECTION SERVICES

PCAB
PHARMACY COMPOUNDING ACCREDITATION BOARD

FOR PROVIDERS.
BY PROVIDERS.™

COMPOUNDING COMPLIANCE

PHARMACY

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AIS ACHC INSPECTION SERVICES

PCAB® PHARMACY COMPOUNDING ACCREDITATION BOARD

ACCREDITATION COMMISSION *for* HEALTH CARE

855-YES-ACHC (855-937-2242) →**achc.org**

January 13, 2015

Mr. Andrew Funk
Iowa Board of Pharmacy

Dear Mr. Funk,

Re: Compounded Drugs – What tools can a state utilize to preserve access while at the same time fulfilling the mission of protecting public safety?

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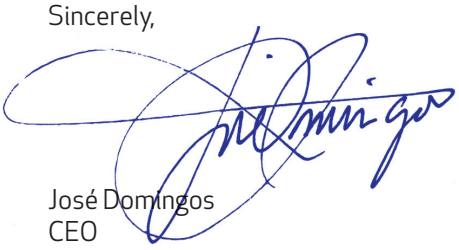
We would like to provide more information on how PCAB Accreditation can be the difference and would appreciate the opportunity to present materials at an upcoming board meeting. Minimally, your board will be better informed in order to make decisions that best suit your goals. Please contact me toll free at 855-937-2242 to choose a time that is mutually acceptable, given that we are aligned in our goal to improve both patient and pharmacy employee safety. Thank you for your consideration.

Sincerely,



José Domingos
CEO

COMPOUNDING COMPLIANCE

RECOMMENDATION

As a leading accreditation organization, ACHC is committed to providing services that facilitate the highest quality of patient care and safety. In light of increased scrutiny in the pharmacy compounding industry after recent events, ACHC has made considerable efforts to offer compliance solutions that specifically address the risks unique to compounded medications.

Recent developments with ACHC's Pharmacy service offerings include the release of ACHC Inspection Services (AIS) and the integration of PCAB Accreditation for non-sterile and sterile compounding. The range of compliance solutions is designed to offer regulatory bodies and providers flexibility without compromising quality.

ACHC recognizes the challenges that state boards of pharmacy face in their effort to ensure the safety of residents. The high risk associated with compounding medications necessitates the inspection of each facility. That said, resources to perform inspections are often strained due to the fragmented nature of the industry. ACHC compliance solutions allow state boards of pharmacy to outsource the inspection process to a highly qualified organization at no cost to the boards or the public.

By requiring compounding pharmacies to undergo PCAB Accreditation, boards of pharmacy can rest assured that compounding pharmacies have demonstrated continuous compliance with applicable USP standards. While other inspection programs are available to review compounding practices, they are not designed to enhance the pharmacy as they do not compel the pharmacy to address the root causes of their deficiencies, nor do these programs require the annual demonstration of continuous compliance required by PCAB.

ABOUT ACHC

MISSION STATEMENT

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.

BEHIND THE MISSION

We will maintain highly relevant standards, including making sure they are easy for providers to access and interpret.

Working with ACHC is not strictly about the end result. We strive to give our customers a positive experience every time we interact .

For our customers, accreditation by ACHC is an investment, and they measure it like one. It is our job to make sure doing business with us is always worth the expense.

VALUES

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

BEHIND THE VALUES

Although these values may seem rather simple, we believe that living every day by these core principles ultimately produces the intended end results, whether we are applying them to our customers or in our interactions with each other.

Collaborative relationships produce results that could never be achieved individually. This concept of collaboration is also what ultimately makes our partnerships successful. We enter every relationship with the intent of mutual benefit. Win-Win is the only sustainable model.

We must strive to accommodate our customers' needs and to maintain our flexibility in helping them achieve our mutual goals without compromising the quality and integrity of our product. That flexibility will turn customers into advocates.

We believe that the perceived and actual experience our customers have with us is the reason they engage our services and why they renew with us, respectively. That experience is not defined by an event but rather a series of interactions. Every employee needs to understand the importance and the expectation that they will be personally held responsible for positively contributing to the experience at each touch point.

FOR PROVIDERS. BY PROVIDERS.

As a nationally recognized accreditation organization, ACHC understands the importance of offering customized standards that are designed for the individual services our customers provide. Our collaborative approach to accreditation has gained ACHC respect and recognition for being uniquely committed to healthcare providers. ACHC offers:

- Relevant standards created by industry experts – all who have been providers themselves
- Surveys that include an evaluation of adherence to national and state regulations
- Program-specific resources to assist providers throughout the accreditation process
- Account Advisors who are committed to providing the best possible experience

THE ACHC DIFFERENCE

At ACHC, our entire team is committed to helping our customers achieve and maintain accreditation, as well as benefit from improved efficiencies and industry best practices. Our commitment is supported by:

- Medicare Deeming Authority for Home Health, Hospice, and DMEPOS
- Service-specific standards that are relevant and realistic for providers' business operations
- Clear, concise language with helpful interpretations for implementing and maintaining compliance
- National recognition by most major third-party payors

ACHC QUALITY

Much like the providers we serve, ACHC holds itself to the highest quality of standards in everything that we do. By making quality a central focus of our organization, we are able to design programs and services that provide our customers with the ability to deliver consistent, high-quality care. ACHC continuously evaluates its quality performance through the following internal and external assessments:

- ISO 9001:2008 certification
- Quarterly evaluation of ACHC's performance conducted by the Centers for Medicare & Medicaid Services (CMS)
- Monthly internal audits to ensure continuous compliance and performance improvement

ABOUT ACHC

CUSTOMER SERVICE

At ACHC, each employee is dedicated to providing the best possible experience before, during, and after the accreditation process. The entire organization is committed to going above and beyond in the way we communicate and work with our customers in order to build a collaborative partnership that results in an exceptionally positive accreditation experience. We strongly believe that the customer experience is an essential part of our business.

KNOWLEDGEABLE SURVEYORS

ACHC provides a consultative survey experience through its network of knowledgeable Surveyors who offer guidance with industry-specific best practices. In following this approach, it is our goal to maintain strict quality standards while delivering the best possible accreditation experience. ACHC Surveyors offer:

- Direct industry experience in the programs for which they conduct surveys
- Knowledge from ongoing, mandatory training to ensure compliance with all policies, procedures, and standards
- Evidence-based best practices to improve business operations
- A friendly, consultative approach throughout the entire survey

TIMELINESS OF SURVEY

At ACHC, we understand that the timing of an accreditation survey can impact business goals. To help our customers better manage their business operations, ACHC offers a streamlined accreditation process that is designed to align with our customers' needs. ACHC surveys include:

- Initial on-site survey conducted within 90 days of receiving signed contract
- Proactive renewal process:
  - Timely outreach that ensures continuous accreditation
  - Surveys conducted no later than 60 days prior to accreditation expiration date

ACHC RESOURCES

As a leading accreditation organization, ACHC believes that continuing education for providers is necessary to achieve the highest quality of patient care. Through ACHC's Accreditation University, we strive to keep our customers informed of the latest industry news with a variety of educational resources. Our customers have access to:

- Hands-on accreditation workshops designed for new and existing customers
- Corporate workshops: "Train the Trainer"
- Ongoing compliance with valuable industry-specific updates
- Extensive multimedia resources:
  - FREE webinars, podcasts, whiteboard presentations, and blogs
- *ACHC Accreditation Guide to Success* workbooks:
  - Program-specific workbooks that include helpful hints for each standard, process tips, and audit tools for survey preparation

HISTORY OF ACHC

Founded in 1986, Accreditation Commission for Health Care (ACHC) is a not-for-profit organization created for providers, by providers. ACHC offers an innovative approach to community-based accreditation while remaining receptive to our customers' needs and providing the services required of them.

The following time line provides a quick reference of the 29-year history of ACHC and its milestones.

1980-1989

- Incorporated in 1986 as the North Carolina Accreditation Commission for In-Home Aide Services (NCACIAS).

1990-1999

- The name of the organization is changed to the Accreditation Commission for Home Care, Inc.
- Board approves release of accreditation standards for Home Health, Home Infusion, Private Duty Nursing, and Home Medical Equipment.
- Preparation for national expansion is initiated through recognition from the National Commission of Quality Assurance (NCQA).
- ACHC has accredited organizations in 17 states.
- Board approves release of accreditation standards for Hospice, Specialty Pharmacy, and Fitter Services.

2000-2009

- ACHC's Quality Management System becomes certified to International Organization for Standardization (ISO) 9001:2008 standards.
- ACHC has accredited organizations in 45 states with patients being served in all 50 states, Puerto Rico and Guam.
- The name of the organization is changed to the Accreditation Commission for Health Care, Inc. (ACHC).
- ACHC receives Commitment Level 2 for Malcolm Baldrige National Quality Award standards from the North Carolina Awards for Excellence program.
- Centers for Medicare & Medicaid Services (CMS) approves ACHC for "Deeming Authority" for Hospice, Home Health and DMEPOS.
- Board approves release of accreditation standards for Sleep Lab/Center.
- ACHC's Quality Management System becomes certified to International Organization for Standardization (ISO) 9001:2008 standards.
- ACHC is selected to appear on Inc. Magazine's "Inc. 5000" list of the nation's fastest-growing private companies in America.
- ACHC elects to adopt the Malcolm Baldrige Criteria in its continued efforts to promote performance excellence.

ABOUT ACHC

2010-PRESENT

- ACHC celebrates 28 years of service.
- ACHC wins Ovation Award for HR Excellence.
- Headquarters moved to Cary, NC.
- Behavioral Health Accreditation Standards are launched.
- Board approves release of Long Term Care Pharmacy Accreditation Standards.
- ACHC forms a partnership with DNV Healthcare that allows hospitals and health systems to seek single-source accreditation for both hospital and ancillary services.
- ACHC Hospice Accreditation receives continued recognition by CMS.
- PCAB Accreditation becomes a service of ACHC, offering Non-Sterile Compounding (ref. USP <795>) and Sterile Compounding (ref. USP <797>).
- ACHC launches ACHC Inspection Services (AIS), a division of ACHC.

ABOUT ACHC

PROGRAMS & SERVICES

HOME HEALTH

BHHC—Psychiatric/Behavioral Health Home Care
HHA—Home Health Aide
SW—Social Work
OT—Occupational Therapy
PT—Physical Therapy
SN—Skilled Nursing
ST—Speech Therapy

HOSPICE

HIC—Hospice Inpatient Care
HSP—Hospice Care

PRIVATE DUTY

PDA—Private Duty Aide
PDC—Private Duty Companion/ Homemaker
PDIN—Private Duty Infusion Nursing
PDN—Private Duty Nursing
PDOT—Private Duty Occupational Therapy
PDPT—Private Duty Physical Therapy
PDST—Private Duty Speech Therapy
PDSW—Private Duty Social Work

BEHAVIORAL HEALTH

ACTT—Assertive Community Treatment Team
ARS—Assessment and Referral Services
CMGT—Case Management
CS—Community Support
DTX—Day Treatment
IIH—Intensive In-Home
IOTX—Intensive Outpatient Treatment
OTX—Outpatient Treatment
PHS—Partial Hospitalization Services
PSR—Psychosocial Rehabilitation
PSS—Personal Support Services
PVS—Prevention Services
RTX—Residential Treatment
SES—Supported Employment Services
SGL—Supervised Group Living

Pending release*

BHH—Behavioral Health Home
CRS—Crisis Response Services
FCS—Foster Care Services
ICS—Integrated Care Services
RCS—Respite Care Services

*Contact ACHC for more information.

PHARMACY

AIC—Ambulatory Infusion Center
IRN—Infusion Nursing
IRX—Infusion Pharmacy
SRX—Specialty Pharmacy
LTC—Long Term Care Pharmacy

PCAB Accreditation

CFNS—Non-Sterile Compounding (Ref. USP <795>)
CFST—Sterile Compounding (Ref. USP <797>)

AIS—ACHC Inspection Services

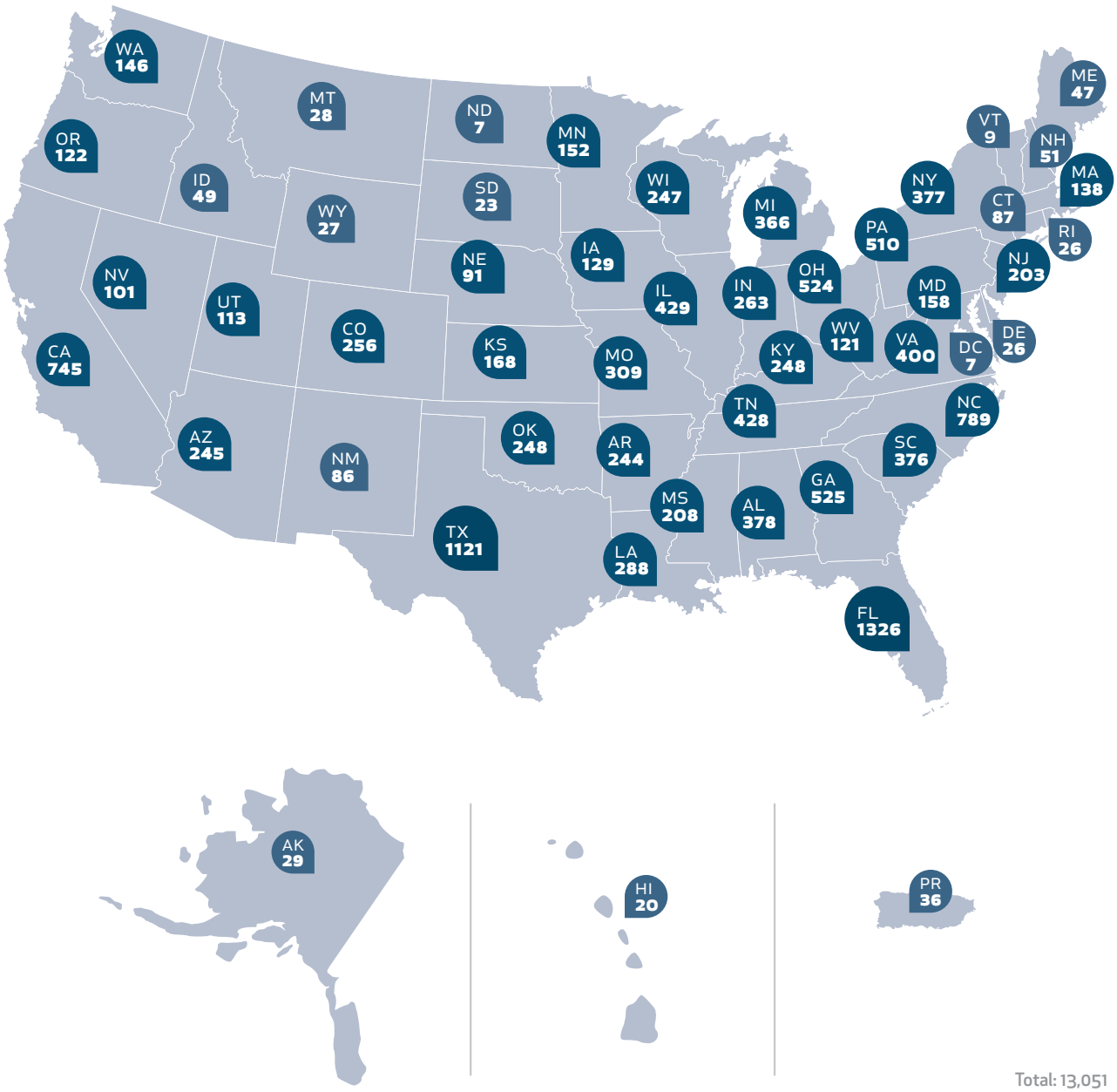
DMEPOS

CR—Community Retail
CRCS—Clinical Respiratory Care Services
Fitter—Fitter
HME—Home/Durable Medical Equipment
MSP—Medical Supply Provider
RTS—Complex Rehabilitation and Assistive Technology Supplier

SLEEP

SLC—Sleep Lab/Center
HST—Home Sleep Testing

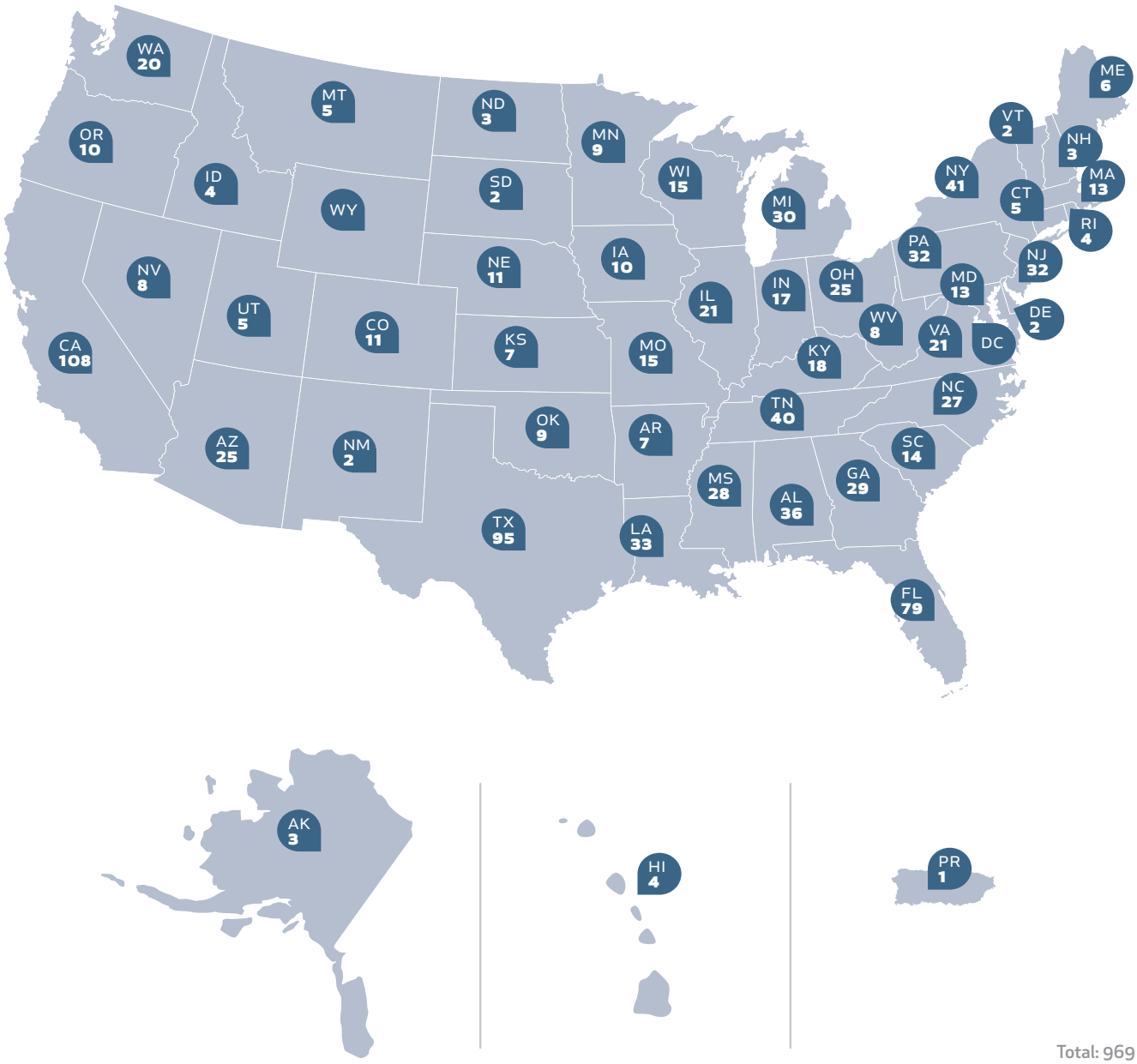
ACCREDITED LOCATIONS BY STATE



Total: 13,051
Revised November, 2015

ABOUT ACHC

ACCREDITED PHARMACY LOCATIONS BY STATE



Total: 969
Revised November, 2015

PCAB & AIS

PCAB RECOMMENDATION

As a leading accreditation organization, ACHC is committed to providing services that facilitate the highest quality of patient care and safety. In light of increased scrutiny in the pharmacy compounding industry after recent events, ACHC has made considerable efforts to offer compliance solutions that specifically address the risks unique to compounded medications.

Recent developments with ACHC's Pharmacy service offerings include the release of ACHC Inspection Services (AIS) and the integration of PCAB Accreditation for non-sterile and sterile compounding. The range of compliance solutions is designed to offer regulatory bodies and providers flexibility without compromising quality.

ACHC recognizes the challenges that state boards of pharmacy face in their effort to ensure the safety of residents. The high risk associated with compounding medications necessitates the inspection of each facility. That said, resources to perform inspections are often strained due to the fragmented nature of the industry. ACHC compliance solutions allow state boards of pharmacy to outsource the inspection process to a highly qualified organization at no cost to the boards or the public.

By requiring compounding pharmacies to undergo PCAB Accreditation, boards of pharmacy can rest assured that compounding pharmacies have demonstrated continuous compliance with applicable USP standards. While other inspection programs are available to review compounding practices, they are not designed to enhance the pharmacy as they do not compel the pharmacy to address the root causes of their deficiencies, nor do these programs require the annual demonstration of continuous compliance required by PCAB.

It is apparent that boards of pharmacy are not simply looking to check a box but are instead looking for solutions that make a real difference. Choosing an inspection program, whether it is NABP's VPP or ACHC's AIS program, will produce an episodic hurdle that simply needs to be overcome. It does not produce the comprehensive, substantive impact boards of pharmacy desire. Only PCAB Accreditation will provide that result. By partnering with ACHC, states may recognize the following benefits:

COST SAVINGS:

States are not responsible for the cost of performing inspections

RESOURCE MANAGEMENT:

States are not responsible for maintaining the resources necessary to conduct pharmacy inspections allowing for better resource allocation

CONSISTENCY:

AIS can efficiently provide consistent inspections on a national basis through its network of qualified pharmacist inspectors

RELIABILITY:

AIS utilizes the experience of ACHC Accreditation to establish a proven process for inspections

INFRASTRUCTURE:

AIS has demonstrated that it has the infrastructure to manage the demand for pharmacy inspections

ACHC PHARMACY SURVEYORS/INSPECTORS

SURVEYOR REQUIREMENTS

ACHC requires all pharmacy Surveyors who conduct surveys of compounding pharmacies to meet the following criteria:

- Licensed Pharmacist
- Active professional license
- A minimum of five years of experience in sterile and non-sterile pharmacy compounding with at least two years in a management role
- Comprehensive training in surveying sterile compounding pharmacies prior to, or within two weeks of hire
- A minimum of two precepted training surveys
- Ongoing education by ACHC pharmacy experts

ACHC has a total of 26 trained and qualified pharmacy Surveyors, including the recent addition of PCAB Surveyors. The following provides a sample of the experience held by ACHC Surveyors:

- Appointed to the USP Expert Panel for sterile compounding
- Received Pharmacist of the Month award from the Professional Compounding Centers of America (PCCA)
- Awarded recognition as Fellow of American Society of Health-System Pharmacists (ASHP)
- 29 years of sterile compounding experience
- More than 250 surveys completed for pharmacies compounding sterile preparations
- A member of the ASHP Specialty Advisory Group (SAG) on Home Infusion

PCAB & AIS

PROGRAM COMPARISON GRID

	ACHC		
Features	**PCAB**	**AIS**	**VPP**[1]
Safety			
Review of USP <795>	✓	✓	✓
Review of USP <797>	✓	✓	✓
Additional Requirements	Does the pharmacy's Performance Improvement (PI) Plan meet key criteria, including (but not limited to): ▪ How the plan will be conducted ▪ Responsible individuals ▪ Which tasks will be reviewed ▪ Outcome goals ▪ Root cause analysis ▪ Review of patient complaints and adverse events ▪ PI outcomes	Does the pharmacy have a PI Plan? Yes/No	Does the pharmacy have a PI Plan? Yes/No
Pharmacist Surveyors	✓	✓	
Annual Verification of compliance	✓		
Administrative			
Customized to state requirements	✓	✓	✓
Prompt access to findings[2]	✓	✓	✓
Survey cycle3	3 years	State dependent	State dependent
Base price	$8,500	$2,995	$3,000
Post-survey correction	Pharmacy submits Plan of Correction (POC)[4]	State dependent	Pharmacy provides written response
Payor Recognition	Many payors recognize PCAB Accreditation as benchmark of quality		
Prescriber Recognition	Many physicians refer patients to PCAB Accredited pharmacies		

1. VPP information gathered from NABP.org as of 10/2015
2. For PCAB, findings are available with pharmacy's permission or regulatory requirement
3. Inspection requirements typically follow a 2-year cycle
4. Plan of Correction requirements are detailed on Process Comparison Grid

PROCESS COMPARISON GRID

	PCAB	AIS
Type	Accreditation	Inspection
	PCAB surveys provide a consultative review of compliance with PCAB standards, referencing USP <795>/<797>. Surveyor documents deficiencies along with corrective action required.	AIS Inspections provide a data collection service built on requirements for USP <795>/<797>. Findings are recorded in a YES/NO format.
Review Process	An independent reviewer analyzes survey findings in order to provide consistency and appropriateness. A review committee determines the Accreditation Decision.	Minimal review is required. The findings are submitted to the State Board or appropriate agency. AIS provides a recommendation (not decision) based on state preferences.
	The pharmacy formally responds to deficiencies with Plan of Correction (POC) and appropriate evidence. This process allows for dialogue between PCAB and the pharmacy to mitigate deficiencies.	The State Board receives the completed inspection form and determines outcome/licensing decision.
	The Plan of Correction (POC) defines what the pharmacy is going to do, when it will be done, and how it will be done. Select evidence is required to complete the process. All findings must be adequately addressed prior to approving POC. The POC helps pharmacies eliminate gaps between their practice and the actual requirement.	
	A Review committee analyzes the submitted Plan of Correction and evidence and provides a written response to the pharmacy.	
	A decision is made whether to require additional evidence, request evidence of continual compliance, or follow up with a re-survey.	
Follow-Up	Annual verification of compliance	N/A
	The Pharmacy must demonstrate continuous compliance through submission of documentation including: Equipment training/competency, New personnel training, ongoing personnel competency, sterility and endotoxin summary log (sterile only), equipment calibration and certification, quality control procedures, sampling of formulation records, overview of performance improvement.	
	The annual verification of compliance demonstrates continued compliance in between on-site surveys.	

PCAB & AIS

FOR IMMEDIATE RELEASE

November 10, 2014

Media Contact:

Kevin O'Connell

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ACHC Announces the Launch of ACHC Inspections Services (AIS)

Cary, NC- Accreditation Commission for Health Care (ACHC) today announced the launch of ACHC Inspection Services (AIS), a new division focused on providing inspection services for healthcare organizations on behalf of state regulatory bodies. The service is designed to verify the compliance of healthcare providers in order to provide assurance to regulatory bodies, physicians, and patients.

"The AIS division is committed to providing a compliance solution that aligns with the needs of regulatory bodies and providers to facilitate the highest-quality of patient care and safety," said ACHC CEO, José Domingos. "Our extensive accreditation experience has left us well-equipped to conduct inspections and we look forward to working with states and providers alike in the administration of the inspection process."

Current trends in the healthcare industry are seeking solutions for providers to demonstrate compliance with state and federal regulations in order to ensure high-quality products and services in addition to patient safety. AIS serves as an independent, third party review organization for healthcare organizations seeking to demonstrate compliance for the fulfillment of state licensure requirements. The service is comprised of highly-qualified, industry-specific professionals that conduct thorough inspections on behalf of state regulatory bodies.

The launch of the new division comes after ACHC's approval to perform inspections on behalf of the Texas State Board of Pharmacy. The Texas State Board of Pharmacy Inspection program provides compounding inspections for non-resident pharmacies that ship sterile preparations into Texas. ACHC has broad and extensive experience in the area of pharmacy compliance, including accreditation programs for non-sterile and sterile compounding, infusion, specialty, and long term care pharmacy services. The organization also offers a range of resources designed to help healthcare providers achieve and maintain compliance, including workbooks, workshops, and compliance checklists.

Organizations interested in AIS inspection services can learn more at AISinspections.org.

ACHC is a non-profit accreditation organization that has stood as a symbol of quality and excellence since 1986. The organization has CMS Deeming Authority for Home Health, Hospice, and DMEPOS and a Quality Management System that is certified to ISO 9001:2008. ACHC is the provider's choice for accreditation because of their personal Accreditation Advisors, relevant and realistic standards, competitive pricing, and a friendly, consultative approach to accreditation. Accreditation by ACHC reflects an organization's dedication and commitment to meeting standards that facilitate a higher level of performance and patient care.

For more information on ACHC's accreditation programs, or to download ACHC accreditation standards, please visit www.achc.org or contact them at customerservice@achc.org or 855-937-2242.

PCAB & AIS

FOR IMMEDIATE RELEASE

June 30, 2014

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PCAB Accreditation Becomes a Service of ACHC

Cary, NC- Accreditation Commission for Health Care (ACHC) and Pharmacy Compounding Accreditation Board (PCAB) have entered into an agreement to transfer certain PCAB assets to ACHC, whereby ACHC will administer the PCAB accreditation program for all qualified PCAB-accredited and in-process pharmacy accounts. Under terms of the agreement, PCAB Accreditation will become a service of ACHC. ACHC will honor the accreditation status of all qualified PCAB-accredited (and in-process) pharmacies according to current PCAB standards through their expiration dates.

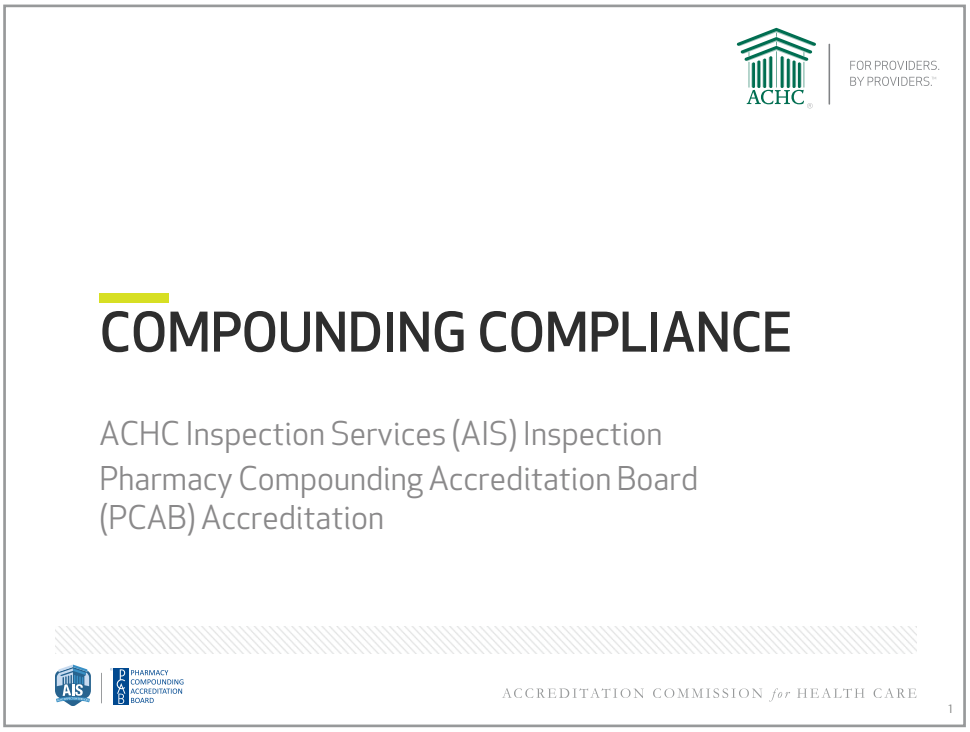
"Compounding pharmacies should view this as a positive indicator of the compliance model adapting to the changing needs of patients and providers," according to B. Douglas Hoey, RPh, MBA, PCAB's President. "PCAB was formed in 2007 as the first accreditation organization to recognize and exclusively address the unique needs of the compounding industry. Over time, and especially in the wake of the meningitis tragedy in 2012, the focus has shifted, rightly, to the need to ensure compliance while addressing the diversity in the provider community. PCAB and ACHC have been communicating for some time about how to best accomplish that goal. This agreement directs us to the best outcome for all parties."

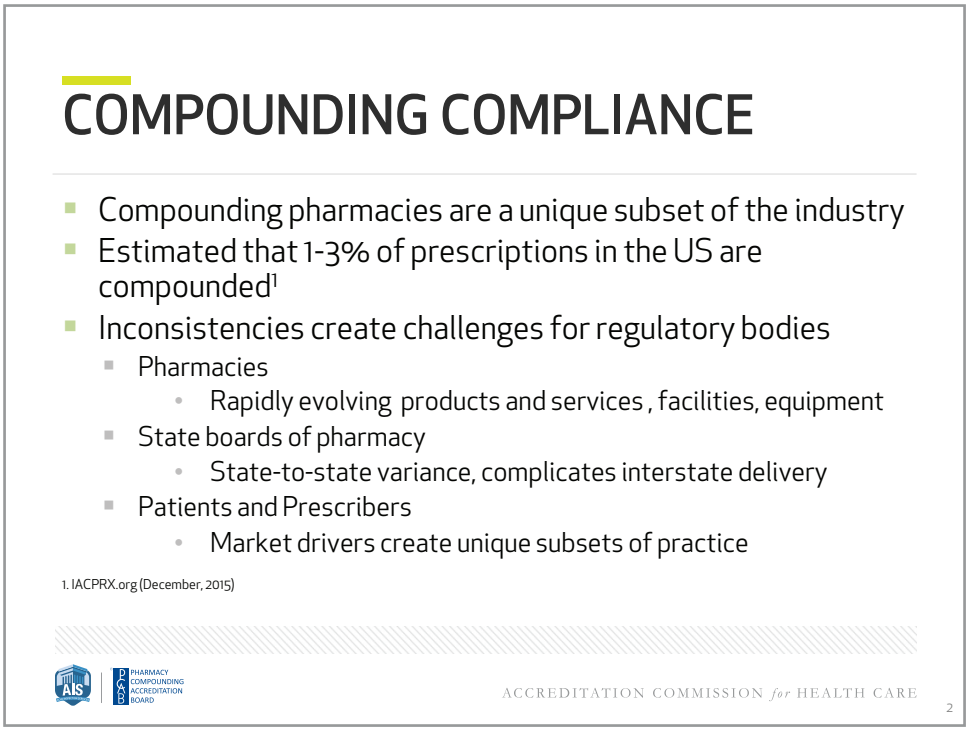
According to ACHC CEO, José Domingos, "ACHC is well-equipped to ensure that PCAB customers will continue to realize the benefits of compliance through accreditation. It should also signal to the healthcare community that two respected and forward-thinking accreditation organizations have taken steps to ensure that safety and compliance needs are met in the most efficient and effective manner going forward, with the expectation that regulatory/payor-driven conditions will increase demand for compliance solutions."

PCAB is a non-profit organization that provides a voluntary accreditation program for compounding pharmacies nationwide. Formed by eight of the nation's leading pharmacy organizations, PCAB promotes, develops and maintains principles, policies and standards for improving the quality of pharmacy compounding nationwide. For more information, visit www.pcab.org.

ACHC is a non-profit accreditation organization that has stood as a symbol of quality and excellence since 1986. The organization has CMS Deeming Authority for Home Health, Hospice, and DMEPOS and a Quality Management System that is certified to ISO 9001:2008. ACHC is the provider's choice for accreditation because of their personal Accreditation Advisors, relevant and realistic standards, competitive pricing, and a friendly, consultative approach to accreditation. Accreditation by ACHC reflects an organization's dedication and commitment to meeting standards that facilitate a higher level of performance and patient care. For more information on ACHC's accreditation programs, or to download ACHC accreditation standards, please visit www.achc.org or contact them at customerservice@achc.org or 855-937-2242.

PRESENTATION





COMPOUNDING COMPLIANCE

Involvement of multiple agencies creates confusion

- State Boards of Pharmacy
- Federal Agencies
  - Food and Drug Administration (FDA)
    - DQSA – 503A vs. 503B?
    - Warning letters and Form 483 observations
  - Drug Enforcement Agency (DEA)
  - Centers for Disease Control and Prevention (CDC)
  - Occupational Safety and Health Administration (OSHA)
- USP

COMPOUNDING COMPLIANCE

- U.S. Pharmacopeial (USP) practice guidelines
  - Non-governmental standard-setting organization, often cited by regulators
  - Considered by experts to be the minimum standard by which a pharmacy should operate
  - Boards of pharmacy may require full or partial compliance
  - USP<795> - non-sterile compounding
  - USP<797> - sterile compounding
  - Associated USP Chapters: <85>, <71>, <1163>
- HOWEVER, USP is non-regulatory

COMPOUNDING COMPLIANCE

- Accreditation is one solution that pharmacies have chosen to demonstrate compliance
  - PCAB – The industry's most comprehensive compliance solution
- Inspection services
  - ACHC Inspection Services
  - National Association of Boards of Pharmacy (NABP) – Verified Pharmacy Program

ACCREDITATION COMMISSION *for* HEALTH CARE

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ACHC PHARMACY SURVEYORS/ INSPECTORS

- Requirements for compounding pharmacy Surveyors/Inspectors include
  - Registered Pharmacist with an active professional license
  - Minimum of five years of experience in sterile and/or non-sterile pharmacy compounding with at least two years in a management role
  - State-specific training conducted as required
  - A minimum of two precepted training surveys and ongoing education
- ACHC has a total of 22 trained and qualified pharmacy Surveyors, including PCAB Surveyors
  - Examples of the experience held by ACHC Surveyors include
    - Appointed to the USP expert panel for sterile compounding
    - 29 years of sterile compounding experience
    - Conducted more than 250 surveys of pharmacies compounding sterile preparations

ACCREDITATION COMMISSION *for* HEALTH CARE

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PROGRAM COMPARISON

	ACHC		
Features	**PCAB**	**AIS**	**VPP[1]**
Safety			
Review of USP <795>	✓	✓	✓
Review of USP <797>	✓	✓	✓
Additional Requirements	Does the pharmacy's Performance Improvement (PI) Plan meet key criteria, including (but not limited to): • How the plan will be conducted • Responsible individuals • Which tasks will be reviewed • Outcome goals • Root cause analysis • Review of patient complaints and adverse events • PI outcomes	Does the pharmacy have a PI Plan? Yes/No	Does the pharmacy have a PI Plan? Yes/No
Pharmacist Surveyors	✓	✓	
Annual Verification of compliance	✓		
Administrative			
Customized to state requirements	✓	✓	✓
Prompt access to findings[2]	✓	✓	✓
Survey cycle[3]	3 years	State dependent	State dependent
Base price	$8,500	$2,995	$3,000
Post-survey correction	Pharmacy submits Plan of Correction (POC)[4]	State dependent	Pharmacy provides written response
Payor Recognition	Many payors recognize PCAB Accreditation as benchmark of quality		
Prescriber Recognition	Many physicians refer patients to PCAB Accredited pharmacies		

1. VPP information gathered from NABP.org as of 10/2015
2. For PCAB, findings are available with pharmacy's permission or regulatory requirement
3. Inspection requirements typically follow a 2-year cycle
4. Plan of Correction requirements are detailed on Process Comparison Grid

AIS
PCAB PHARMACY COMPOUNDING ACCREDITATION BOARD

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PROCESS COMPARISON

	PCAB	AIS
Type	Accreditation	Inspection
	PCAB surveys provide a consultative review of compliance with PCAB standards, referencing USP <795>/<797>. Surveyor documents deficiencies along with corrective action required.	AIS Inspections provide a data collection service built on requirements for USP <795>/<797>. Findings are recorded in a YES/NO format.
Review Process	An independent reviewer analyzes survey findings in order to provide consistency and appropriateness. A review committee determines the Accreditation Decision.	Minimal review is required. The findings are submitted to the State Board or appropriate agency. AIS provides a recommendation (not decision) based on state preferences.
	The pharmacy formally responds to deficiencies with Plan of Correction (POC) and appropriate evidence. This process allows for dialogue between PCAB and the pharmacy to mitigate deficiencies.	The State Board receives the completed inspection form and determines outcome/licensing decision.
	The POC defines what the pharmacy is going to do, when it will be done, and how it will be done. Select evidence is required to complete the process. All findings must be adequately addressed prior to approving POC. The POC helps pharmacies to eliminate gaps between their practice and the actual requirement.	
	A Review committee analyzes the submitted Plan of Correction and evidence and provides a written response to the pharmacy.	
	A decision is made whether to require additional evidence, request evidence of continual compliance, or follow up with a re-survey.	
Follow-Up	Annual verification of compliance	N/A
	The Pharmacy must demonstrate continuous compliance through submission of documentation including: Equipment training/competency, New personnel training, ongoing personnel competency, sterility and endotoxin summary log (sterile only), equipment calibration and certification, quality control procedures, sampling of formulation records, overview of performance improvement.	
	The annual verification of compliance demonstrates continued compliance in between on-site surveys.	

AIS
PCAB PHARMACY COMPOUNDING ACCREDITATION BOARD

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PRESENTATION

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

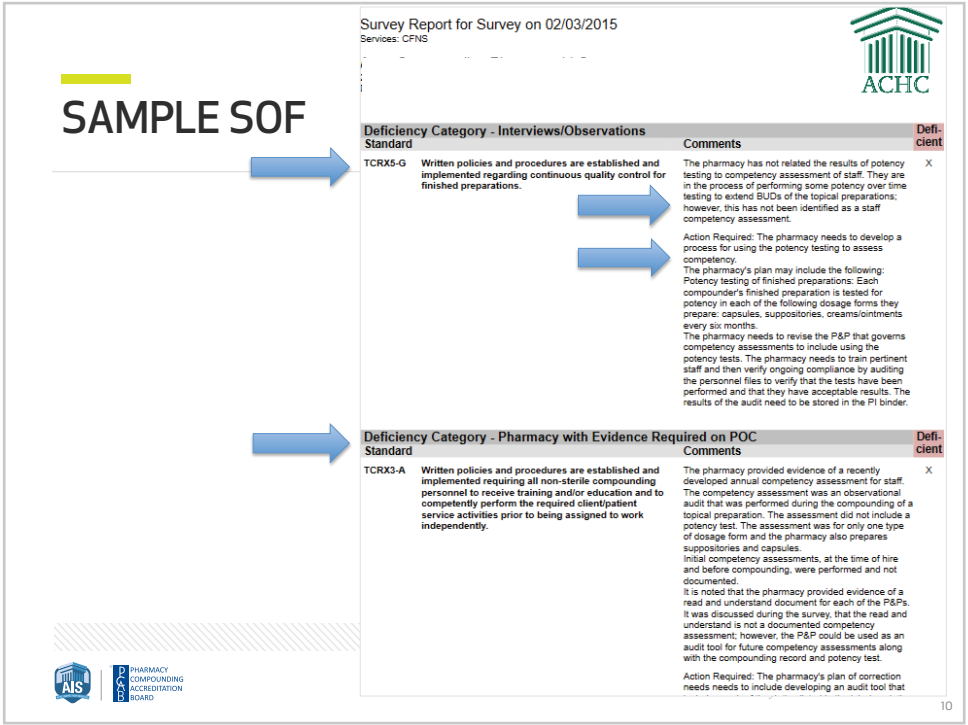
Provider has significant deficiencies to achieve accreditation. An additional on-site visit will be necessary to be eligible for accreditation.

DENIED

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

*For Home Health, Hospice, and Behavioral Health providers, all requirements must be met for full accreditation.

SAMPLE SOF



Survey Report for Survey on 02/03/2015

Services: CFNS

ACHC

Deficiency Category - Interviews/Observations			
Standard		Comments	Deficient
TCRX5-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	Deficient
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.**	The pharmacy provided evidence of a recently developed annual competency assessment for staff. The competency assessment was an observational audit that was performed during the compounding of a topical preparation. The assessment did not include a potency test. The assessment was for only one type of dosage form and the pharmacy also prepares suppositories and capsules. Initial competency assessments, at the time of hire and before compounding, were performed and not documented. It is noted that the pharmacy provided evidence of a read and understand document for each of the P&Ps. It was discussed during the survey, that the read and understand is not a documented competency assessment; however, the P&P could be used as an audit tool for future competency assessments along with the compounding record and potency test. Action Required: The pharmacy's plan of correction needs needs to include developing an audit tool that	X

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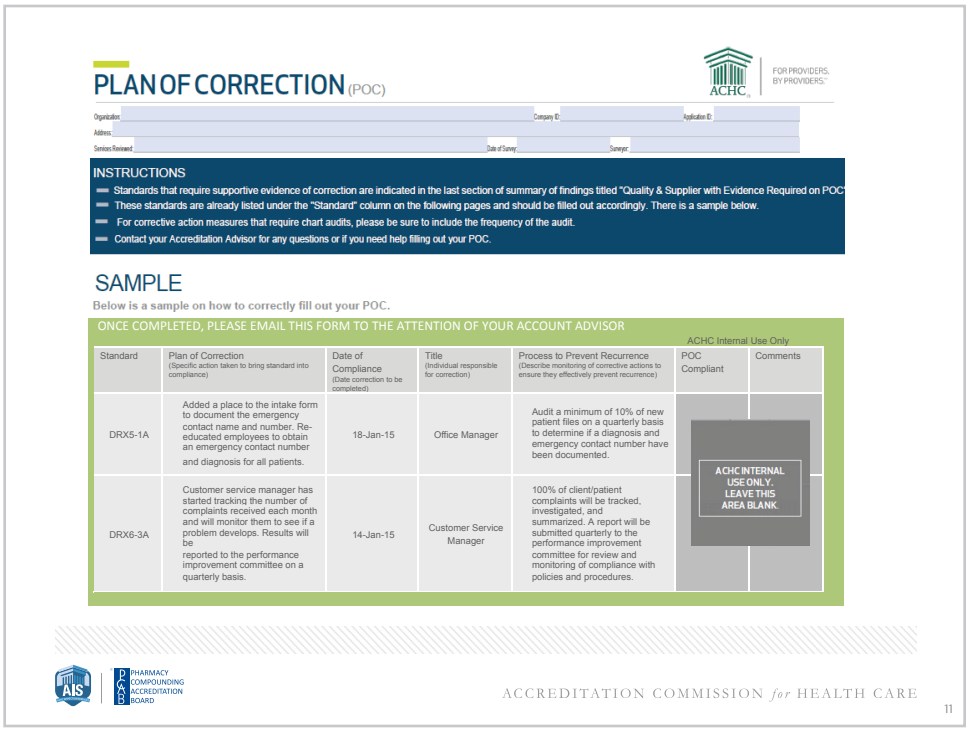

PLAN OF CORRECTION (POC)

ACHC FOR PROVIDERS. BY PROVIDERS.™

Organization: Company ID: Application ID:
Address:
Services Reviewed: Date of Survey: Surveyor:

INSTRUCTIONS

- Standards that require supportive evidence of correction are indicated in the last section of summary of findings titled "Quality & Supplier with Evidence Required on POC"
- These standards are already listed under the "Standard" column on the following pages and should be filled out accordingly. There is a sample below.
- For corrective action measures that require chart audits, please be sure to include the frequency of the audit.
- Contact your Accreditation Advisor for any questions or if you need help filling out your POC.

SAMPLE

Below is a sample on how to correctly fill out your POC.

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

ACHC Internal Use Only

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	Comments
DRX5-1A	Added a place to the intake form to document the emergency contact name and number. Re-educated employees to obtain an emergency contact number and diagnosis for all patients.	18-Jan-15	Office Manager	Audit a minimum of 10% of new patient files on a quarterly basis to determine if a diagnosis and emergency contact number have been documented.	ACHC INTERNAL USE ONLY. LEAVE THIS AREA BLANK.	
DRX6-3A	Customer service manager has started tracking the number of complaints received each month and will monitor them to see if a problem develops. Results will be reported to the performance improvement committee on a quarterly basis.	14-Jan-15	Customer Service Manager	100% of client/patient complaints will be tracked, investigated, and summarized. A report will be submitted quarterly to the performance improvement committee for review and monitoring of compliance with policies and procedures.		

AIS | PCAB PHARMACY COMPOUNDING ACCREDITATION BOARD

ACCREDITATION COMMISSION *for* HEALTH CARE

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ACCREDITATION

Benefits to public

- Improved safety and quality
  - Consistent practices result in improved safety, efficiency, and quality of care
- Risk aversion
  - ACHC provides an added measure of assurance for patient and employee safety in addition to reducing pharmacy risks
- Continuity of service
  - Accreditation facilitates a standardized level of service that includes sound procedures, documentation, and training to ensure consistent performance

AIS | PCAB PHARMACY COMPOUNDING ACCREDITATION BOARD

ACCREDITATION COMMISSION *for* HEALTH CARE

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ACCREDITATION

Benefits to regulatory bodies

- Third party solution
  - Independent 3rd party verifies compliance with industry standards as well as ensure continuous quality improvement
- Cost savings
  - Provider-funded service
- Resource management
  - The accreditation organization maintains the infrastructure to conduct accreditation surveys
- Reliability
  - Accreditation utilizes the extensive experience of industry Surveyors to conduct consistent, thorough surveys
- Transparency
  - Accreditation findings can be shared with key stakeholders

ACCREDITATION COMMISSION *for* HEALTH CARE

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RECOMMENDATION

- Recognize PCAB Accreditation
  - PCAB Accreditation exceeds inspection requirements
  - Established value and proven track record
  - Nationally recognized by third-party payors
  - Prescriber recognition of PCAB
  - Serves as an extension of State Inspectors

ACCREDITATION COMMISSION *for* HEALTH CARE

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FOR PROVIDERS.
BY PROVIDERS.™

ADDITIONAL ACHC INFORMATION

ACCREDITATION COMMISSION *for* HEALTH CARE

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ACHC®

ACCREDITATION COMMISSION *for* HEALTH CARE

ACCREDITATION UNIVERSITY

PHARMACY COMPOUNDING ACCREDITATION BOARD

AIS

ACHC INTERNATIONAL

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ABOUT ACHC

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.

- Nationally recognized accreditation organization with 29 years of experience
- CMS Deeming Authority for Home Health, Hospice, and DMEPOS
- Recognition by major third-party payors
- Approved to perform state licensure surveys
- First accreditation organization with a Quality Management System certified to ISO 9001:2008

ACCREDITATION COMMISSION *for* HEALTH CARE

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ACHC MISSION AND VALUES

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.

Values:

1. Committed to successful collaborative relationships
2. Flexibility without compromising quality
3. Every employee is accountable for their contribution to providing the best possible experience
4. We will conduct ourselves in an ethical manner in everything we do

ACCREDITATION COMMISSION *for* HEALTH CARE

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EXTENSION OF THE EXPERIENCE

- ACHC is committed to providing value to organizations through relevant standards that set quality benchmarks, identify best practices, and promote continuous quality improvement
- Organizations, in turn, comply with these standards, validating their commitment to quality and accountability
- Downstream, providers have the required knowledge and necessary tools to provide the best possible care/service
- The patients benefit

CUSTOMER SATISFACTION

ACHC is committed to providing the best possible **experience.**

99%
of our customers regard their experience with ACHC as positive.

"ACHC was the only organization that made it a positive learning experience."
-DMEPOS PROVIDER, RALEIGH, NC

98%
of our customers would recommend ACHC.

"Our Accreditation Advisor really takes care of us!"
- HOME HEALTH AGENCY, ENGLEWOOD, CO

Customer Satisfaction Survey data gathered from 7/2015-present.

PRESENTATION

ACHC PROGRAMS & SERVICES

HOME HEALTH
BHHC—Psychiatric/Behavioral Health Home Care
HHA—Home Health Aide
SW—Social Work
OT—Occupational Therapy
PT—Physical Therapy
SN—Skilled Nursing
ST—Speech Therapy

HOSPICE
HIC—Hospice Inpatient Care
HSP—Hospice Care

PRIVATE DUTY
PDA—Private Duty Aide
PDC—Private Duty Companion/Homemaker
PDIN—Private Duty Infusion Nursing
PDN—Private Duty Nursing
PDOT—Private Duty Occupational Therapy
PDPT—Private Duty Physical Therapy
PDST—Private Duty Speech Therapy
PDSW—Private Duty Social Work

PHARMACY
AIC—Ambulatory Infusion Center
IRN—Infusion Nursing
IRX—Infusion Pharmacy
SRX—Specialty Pharmacy
LTC—Long Term Care Pharmacy
PCAB Accreditation
CFNS—Non-Sterile Compounding (Ref. USP <795>)
CFST—Sterile Compounding (Ref. USP <797>)
AIS—ACHC Inspection Services

DMEPOS
CR—Community Retail
CRCS—Clinical Respiratory Care Services
Fitter—Fitter
HME—Home/Durable Medical Equipment
MSP—Medical Supply Provider
RTS—Complex Rehabilitation and Assistive Technology Supplier

SLEEP
SLC—Sleep Lab/Center
HST—Home Sleep Testing

BEHAVIORAL HEALTH
ACTT—Assertive Community Treatment Team
ARS—Assessment and Referral Services
CMGT—Case Management
CS—Community Support
DTX—Day Treatment
IIH—Intensive In-Home
IOTX—Intensive Outpatient Treatment
OTX—Outpatient Treatment
PHS—Partial Hospitalization Services
PSR—Psychosocial Rehabilitation
PSS—Personal Support Services
PVS—Prevention Services
RTX—Residential Treatment
SES—Supported Employment Services
SGL—Supervised Group Living
Pending release*
BHH—Behavioral Health Home
CRS—Crisis Response Services
FCS—Foster Care Services
ICS—Integrated Care Services
RCS—Respite Care Services
*Contact ACHC for more information.

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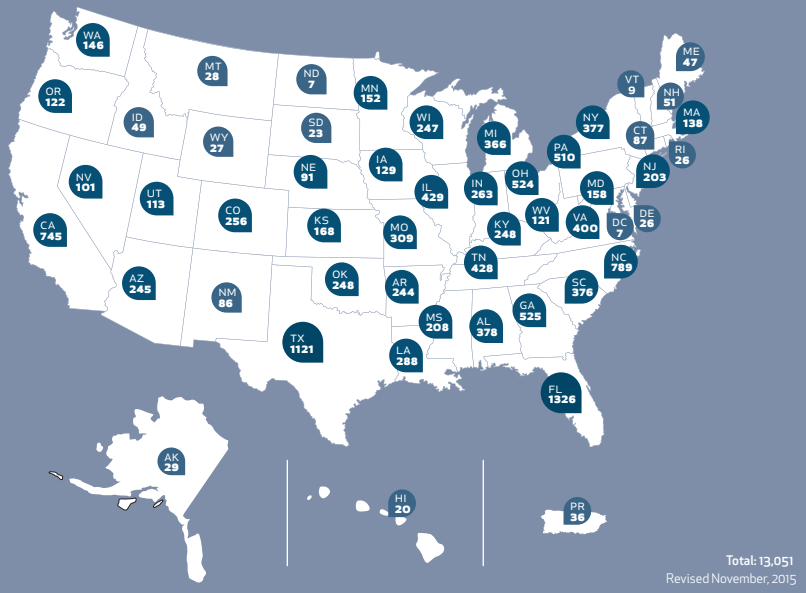
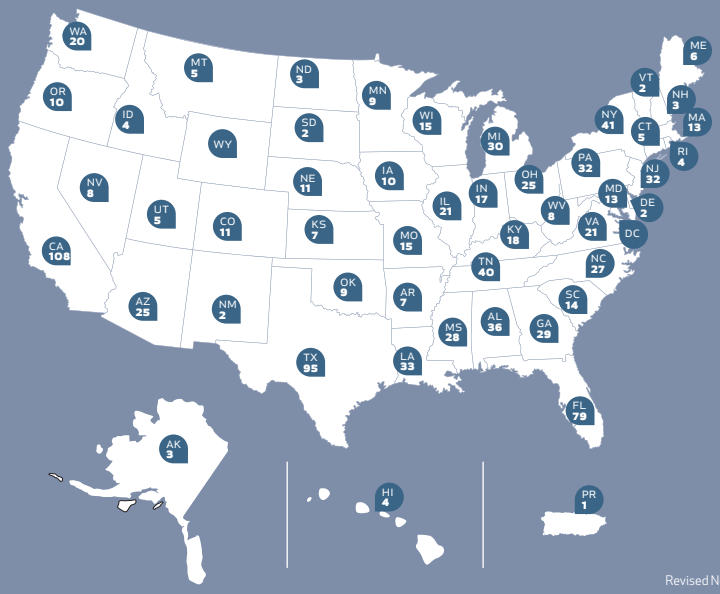
ACHC ACCREDITED LOCATIONS BY STATE



Total: 13,051
Revised November, 2015

PHARMACY ACCREDITED LOCATIONS BY STATE



Total: 969
Revised November, 2015

THANK YOU

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ACCREDITATION COMMISSION *for* HEALTH CARE

ACCREDITATION STANDARDS

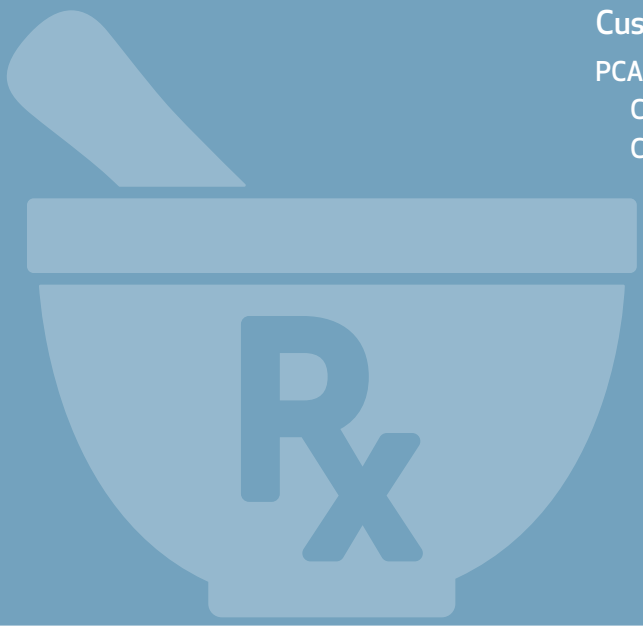
[PHARMACY]

Customized for:

PCAB Accreditation

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

CFST—Sterile Compounding (Ref. USP <797>)



ACCREDITATION STANDARDS Customized for:

PCAB Accreditation

- CFNS—Non-Sterile Compounding (Ref. USP <795>)
- CFST—Sterile Compounding (Ref. USP <797>)

PCAB ACCREDITATION STANDARDS

Customized for Non-Sterile Compounding, Sterile Compounding

PCAB Accreditation Program for Compounding

Pharmacy Compounding is a process by which a pharmacist prepares drugs by combining, mixing, or altering ingredients into a pharmaceutical preparation. Compounding includes the preparation of drugs in anticipation of receiving prescription drug orders based on routine, regularly observed prescribing patterns.

PCAB Accreditation includes two classes of compounding:

- Non-sterile compounding is the practice of preparing medications as result of a practitioner's patient-specific prescription drug order that are designed to be administered by a route of administration that does not require sterility.
- Sterile Pharmacy Compounding is the practice of preparing sterile medications as a result of a practitioner's patient-specific prescription drug order through strict procedures to prevent contamination and maintain patient safety.

PCAB Accreditation for Pharmacy Compounding measures a specific set of process standards that concentrate on the quality and consistency of compounded preparations.

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 location in all locations/branches, and/or in accordance with appropriate regulations or laws. 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
- Pharmacists licenses
- Pharmacy technicians 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 regulations and has access to the pharmacy rules and regulations of all states where pharmacy services are provided.

Evidence: License and/or Permits
Evidence: Observation

Services applicable: CFNS, CFST

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

Interpretation: The pharmacy has access to current UPS 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>.

Evidence: Observation

Services applicable: CFNS, CFST

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 ($10,000.00) or more
- Revocation of Medicare/Medicaid/third-party provider number

Evidence: Board of Director Meeting Minutes
Evidence: Response to Interviews

Services applicable: CFNS, CFST

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

The organization provides all clients/patients with written information that includes a telephone number, contact person, and the organization's process for receiving, investigating and resolving complaints/grievances about its services.

ACHC's telephone number must be provided at the time of initial service. The ACHC phone number requirement is not applicable to organizations if this is their first ACHC survey.

The organization maintains records of complaints/grievances and their outcomes and submits a summary report to the organization's leadership. This information is included in the Performance Improvement (PI) annual report.

Personnel are oriented and familiar with the client/patient complaint/grievance/concern policies and procedures. Personnel assist in implementing the resolution process when needed.

Evidence: Written Policies and Procedures
Evidence: Complaint/Grievance Log
Evidence: Response to Interviews

Services applicable: CFNS, CFST

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.

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.

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.

Evidence: Written Policies and Procedures
Evidence: Training Logs/Competency Assessments
Evidence: Response to Interviews

Services applicable: CFNS

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.

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 service being provided. Competency assessments are conducted initially during orientation and annually thereafter except when required more frequently, for example, for sterile compounding personnel per USP Chapter <797>. Verification of skills is specific to the employee's role and job responsibilities.

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.

Prior to personnel performing sterile compounding, training takes place and competency assessments are performed, which include:

- Didactic training and written testing
- Media-fill testing consistent with the risk level of compounding, in accordance with USP Chapter <797>
- Cleaning and disinfecting procedures
- Hand hygiene and garbing, in accordance with USP Chapter <797>
- Gloved fingertip sampling consistent with the risk level of compounding performed

For personnel who perform sterile compounding, competency assessments are done annually and/or consistent with the risk level of the compounding, which includes:

- Didactic training and written testing
- Media-fill testing consistent with the risk level of compounding, in accordance with USP Chapter <797>
- Cleaning and disinfecting procedures
- Hand hygiene and garbing, in accordance with USP Chapter <797>
- Gloved fingertip sampling consistent with the risk level of compounding performed

Any competency assessment that is not satisfactory requires the individual to be re-trained and the competency assessment repeated. All training and competencies are documented.

Evidence: Written Policies and Procedures
Evidence: Competency Assessment/Initial Training
Evidence: Response to Interviews

Services applicable: CFST

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.

Evidence: Training Logs

Services applicable: CFNS, CFST

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.

Evidence: Training Logs/Files

Services applicable: CFST

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.

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 that they understand the risk of handling hazardous drugs.

Evidence: Personnel Files/Training Logs

Services applicable: CFNS, CFST

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.

Evidence: Written Policies and Procedures
Evidence: Response to Interviews

Services applicable: CFNS, CFST

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

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.

Evidence: Personnel Records
Evidence: Observation

Services applicable: CFNS, CFST

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.

Evidence: Written Policies and Procedures
Evidence: Personnel Files

Services applicable: CFNS, CFST

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.

Evidence: Observation

Services applicable: CFNS, CFST

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.

Evidence: Observation
Evidence: On-Call Schedules
Evidence: Response to Interviews

Services applicable: CFNS, CFST

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

Evidence: Observation

Services applicable: CFNS, CFST

Standard TCRX4-A: A Registered Pharmacist reviews all 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.

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

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.

Evidence: Client/Patient Records
Evidence: Response to Interviews
Evidence: Observation

Services applicable: CFNS, CFST

Standard TCRX4-B: Written policies and procedures are established and implemented which 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.

Evidence: Written Policies and Procedures
Evidence: Observation

Services applicable: CFNS, CFST

Standard TCRX5-A: The organization develops, implements, and maintains an effective, on-going, 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
- 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

Evidence: Written Policies and Procedures/PI Plan

Services applicable: CFNS, CFST

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.

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.

Evidence: Job Description
Evidence: Observation

Services applicable: CFNS, CFST

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.

Evidence: Response to Interviews

Services applicable: CFNS, CFST

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

Evidence: Performance Improvement Activities/Studies

Services applicable: CFNS, CFST

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
- Guidelines for notifying the physician, if applicable

- Follow-up reporting to the administration/board/owner

Written policies and procedures identify the person responsible for collecting incident data and monitoring trends, investigating all incidents, taking necessary follow-up actions and completing appropriate documentation.

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
- 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.

Evidence: Written Policies and Procedures
Evidence: Incident/Variance Reports
Evidence: Performance Improvement Reports

Services applicable: CFNS, CFST

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.

Evidence: Performance Improvement Reports
Evidence: Incident/Variance Reports

Services applicable: CFNS, CFST

PCAB ACCREDITATION STANDARDS

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

Interpretation: The pharmacy establishes an on-going 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

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. For example:

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.

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.

Evidence: Written Policies and Procedures
Evidence: Observation
Evidence: Response to Interviews

Services applicable: CFNS, CFST

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

Interpretation: The organization conducts monitoring of at least one important aspect of the non-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).

Examples of activities include, but are not limited to:

- Monitoring that potency testing is performed in accordance with the organizations written policies and procedures.
- Tracking and classifying quality related events to identify opportunities for improvement.
- Auditing of compounding and formulation records for accuracy and completeness

Evidence: Performance Improvement Reports

Services applicable: CFNS

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

Interpretation: The organization conducts monitoring of at least one important aspect of the 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).

Examples of activities include but are not limited to:

- Monitoring of the finished compounded preparation by testing that the sterility or potency is performed in accordance with the organization's written policies and procedures
- Tracking and classifying quality-related events to identify opportunities for improvement
- Auditing of compounding and formulation records for accuracy and completeness
- Auditing of personnel records to ensure that sterile compounding training and competency assessments are performed as required

Evidence: Performance Improvement Reports

Services applicable: CFST

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.

Evidence: Performance Improvement Reports

Services applicable: CFNS, CFST

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.

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.

Evidence: Written Corrective Action Plans

PCAB ACCREDITATION STANDARDS

Services applicable: CFNS, CFST

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.

Evidence: Performance Improvement Annual Report

Services applicable: CFNS, CFST

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.

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
- 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.

Evidence: Written Policies and Procedures
Evidence: Observation

Services applicable: CFNS, CFST

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.

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

- Identification of clients/patients who received a recalled preparation or component
- Timely and effective notification to affected clients/patients and prescribers
- Tracking of preparations and their components
- External reporting of components and preparation defects
- Safe disposal of recalled medications or preparations

Documentation includes, but is not limited to:

- Records that permit the identification of clients/patients who received a recalled preparation or component
- The manufacturer or source of each ingredient in a preparation and the lot number
- The batch number of the preparation
- Serial numbers used to track equipment
- Records indicating the pharmacy has completed recall(s) in a manner that is consistent with its written policies and procedures, if applicable

Evidence: Written Policies and Procedures
Evidence: Dispensing/Compounding Records
Evidence: Response to Interviews

Services applicable: CFNS, CFST

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.

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

- Storage of pharmaceuticals, components, and compounded preparations in order to maintain their integrity and security
- Establishing appropriate storage temperatures and other storage conditions for pharmaceuticals, components, and compounded preparations
- Monitoring and documenting that storage area(s), refrigerator, and freezer temperatures maintain the appropriate storage conditions
- Regular inspections to remove, quarantine, and dispose of expired pharmaceuticals, components and

compounded preparations
- Defining a quarantine area for pharmaceuticals, components and compounded preparations removed from inventory due to recall, expiration or other reasons
- Contingency plans addressing situations where storage conditions fall outside of established ranges
- Storage and handling of hazardous and potent drugs
- Disposal of pharmaceuticals, components, and compounded preparations
- Labeling of storage containers, including but not limited to name, strength, lot number, transfer date, expiration date and manufacturer or source
- Cleaning and disinfecting of any reusable storage containers

Pharmaceuticals, components and finished compounded preparations are stored in accordance with manufacturer or USP requirements. Storage conditions are monitored wherever these items are stored to ensure that the requirements are met. Pharmaceuticals, components, and finished compounded preparations are stored in the licensed pharmacy, which is accessible only under the supervision of a Registered Pharmacist.

Evidence: Written Policies and Procedures
Evidence: Observation
Evidence: Temperature/Cleaning Logs
Evidence: Response to Interviews

Services applicable: CFNS, CFST

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.

Interpretation: The organization ensures that pharmaceuticals are maintained under appropriate conditions of sanitation, light, and temperatures in the course of deliveries. Where appropriate, the organization uses delivery containers such as coolers and ice packs to maintain the storage conditions in accordance with the manufacturer, USP, and/or other applicable 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.

Shipping methods are tested periodically under the typical conditions the organization's shipments experience (i.e. extreme summer heat and winter cold) to ensure that containers stay within specified temperature requirements.

Evidence: Observation
Evidence: Response to Interviews

Services applicable: CFNS, CFST

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)

Evidence: Written Policies and Procedures
Evidence: Observation
Evidence: Manufacturer's Service Manuals/Guidelines
Evidence: Response to Interviews

Services applicable: CFNS, CFST

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 (CofAs) and Safety Data Sheets (SDSs)
- Criteria for acceptance or rejection of components based upon CofA review and other criteria
- A process for incorporating pertinent CofA data into MFRs and for the retention of CofAs
- 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.
- 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

Evidence: Written Policies and Procedures
Evidence: Record Reviews
Evidence: Observation
Evidence: Response to Interviews

Services applicable: CFNS, CFST

PCAB ACCREDITATION 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.

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 a Master Formulation Record (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
- 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
- A description of the final preparation

Evidence: Written Policies and Procedures
Evidence: Observation
Evidence: Response to Interviews

Services applicable: CFNS, CFST

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.

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)

Evidence: Written Policies and Procedures
Evidence: Observation

Evidence: Response to Interviews

Services applicable: CFNS, CFST

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)
- 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 Master Formulation Record, the Compounding Record, and associated written procedures, documenting any deviation in procedures
- 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
- Performing compounding activities in a manner designed to prevent cross contamination.
- 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 compounding

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.

Evidence: Written Policies and Procedures
Evidence: Observation
Evidence: Response to Interviews

Services applicable: CFNS

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.

The Class I BSC environment(s) are maintained and certified per the manufacturer's requirements. A qualified independent contractor performs certification according to accepted standards for operational efficiency.

Evidence: Written Policies and Procedures
Evidence: Observation
Evidence: Response to Interviews

Services applicable: CFNS

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
- 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

Evidence: Written Policies and Procedures
Evidence: Observation

Services applicable: CFNS

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)
- 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
- 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.

Evidence: Written Policies and Procedures
Evidence: Observation

Services applicable: CFST

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.

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 preparations: A primary engineering control Compounding aseptic isolator (CAI), Compounding aseptic containment isolator (CACI) or Laminar Flow Workstation (LAFW) located outside of a minimum ISO-7 area
- Low and medium risk preparations: A primary engineering control (CAI, CACI, 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 with a minimum airflow of 40 feet per minute that 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 m^3 shall be counted during material transfer, with the particle counter probe located as near to the transfer door as possible without obstructing the transfer
  - 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: A primary engineering control (CAI, CACI, 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 0.02-0.05 inch water column.
- Low, medium and high-risk preparations: A CAI or CACI located in a minimum ISO-8 areas; for high-risk preparations, pre-sterilization procedures are performed in the ISO-8 area.
- The surfaces of ceilings, walls, floors, fixtures, furniture, shelving, counters, and cabinets in the buffer area are impervious, free from cracks and crevices, and 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

Evidence: Observation

Services applicable: CFST

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.

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:

- Pre-sterilization procedures such as weighing, mixing and other manipulations are performed in a minimum Class I BSC.
- 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).

Evidence: Written Policies and Procedures
Evidence: Observation

Services applicable: CFST

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

Interpretation: Cleaning and disinfection 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

- 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
- 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, and action levels

Action levels based on cfu counts for microbial contamination and measures to be taken when action levels are met or exceeded.

Evidence: Written Policies and Procedures
Evidence: Quality Control Records
Evidence: Observations

Services applicable: CFST

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.

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
  - 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 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
  - 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.

Evidence: Written Policies and Procedures
Evidence: Observation
Evidence: Response to Interviews

Services applicable: CFNS

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.

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.
    - 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
    - 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.

Evidence: Written Policies and Procedures
Evidence: Observation

Evidence: Response to Interviews

Services applicable: CFST

Standard TCRX6-R: Written policies and procedures are established and implemented to assure 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.
- 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.
- 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.

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.

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.

Evidence: Written Policies and Procedures
Evidence: Observation
Evidence: Response to Interviews

Services applicable: CFST

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.

Evidence: Client/Patient Records
Evidence: Response to Interviews

Services applicable: CFST

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
- 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

Evidence: Written Policies and Procedures
Evidence: Client/Patient Records

Services applicable: CFNS, CFST

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.

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
- 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

Evidence: Written Policies and Procedures
Evidence: Observation

Services applicable: CFNS, CFST

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).

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 the expiration of the organization's PCAB Accreditation. The documentation requirements are:

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

Evidence: (This is an informational standard only for providers applying for non-sterile compounding for the first time.)

Services applicable: CFNS

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.)

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 the expiration of the organization's 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
- 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
- Summary of records indicating compliance with the requirements of ACHC Standard TCRX6-R in regards 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

Evidence: (This is an informational standard only for providers applying for sterile compounding for the first time.)

Services applicable: CFST

Appendix A: Standard Service Table for Selected Services

Standard	CFNS	CFST
TCRX1-A	X	X
TCRX1-B	X	X
TCRX1-C	X	X
TCRX2-A	X	X
TCRX3-A	X	
TCRX3-B		X
TCRX3-C	X	X
TCRX3-D		X
TCRX3-E	X	X
TCRX3-F	X	X
TCRX3-G	X	X
TCRX3-H	X	X
TCRX3-I	X	X
TCRX3-J	X	X
TCRX3-K	X	X
TCRX4-A	X	X
TCRX4-B	X	X
TCRX5-A	X	X
TCRX5-B	X	X
TCRX5-C	X	X
TCRX5-D	X	X
TCRX5-E	X	X
TCRX5-F	X	X
TCRX5-G	X	X
TCRX5-H	X	
TCRX5-I		X
TCRX5-J	X	X
TCRX5-K	X	X
TCRX5-L	X	X
TCRX6-A	X	X
TCRX6-B	X	X
TCRX6-C	X	X
TCRX6-D	X	X
TCRX6-E	X	X
TCRX6-F	X	X
TCRX6-G	X	X
TCRX6-H	X	X
TCRX6-I	X	
TCRX6-J	X	
TCRX6-K	X	
TCRX6-L		X
TCRX6-M		X
TCRX6-N		X
TCRX6-O		X
TCRX6-P	X	
TCRX6-Q		X
TCRX6-R		X
TCRX6-S		X
TCRX6-T	X	X
TCRX6-U	X	X
TCRX7-A	X	
TCRX7-B		X

Appendix B: Reference Guide for Required Documents, Policies and Procedures

Customized for: CFNS, CFST

Standard #	Documents, Policies and Procedures	Agency Notes
TCRX2-A	Written Policies and Procedures	
TCRX3-A	Written Policies and Procedures	
TCRX3-B	Written Policies and Procedures	
TCRX3-F	Written Policies and Procedures	
TCRX3-H	Written Policies and Procedures	
TCRX4-B	Written Policies and Procedures	
TCRX5-A	Written Policies and Procedures/PI Plan	
TCRX5-E	Written Policies and Procedures	
TCRX5-G	Written Policies and Procedures	
TCRX5-L	Performance Improvement Annual Report	
TCRX6-A	Written Policies and Procedures	
TCRX6-B	Written Policies and Procedures	
TCRX6-C	Written Policies and Procedures	
TCRX6-E	Written Policies and Procedures	
TCRX6-F	Written Policies and Procedures	
TCRX6-G	Written Policies and Procedures	
TCRX6-H	Written Policies and Procedures	
TCRX6-I	Written Policies and Procedures	
TCRX6-J	Written Policies and Procedures	
TCRX6-K	Written Policies and Procedures	
TCRX6-L	Written Policies and Procedures	
TCRX6-N	Written Policies and Procedures	
TCRX6-O	Written Policies and Procedures	
TCRX6-P	Written Policies and Procedures	
TCRX6-Q	Written Policies and Procedures	
TCRX6-R	Written Policies and Procedures	
TCRX6-T	Written Policies and Procedures	
TCRX6-U	Written Policies and Procedures	

CONTINUED COMPLIANCE
STERILE COMPOUNDING

PCAB Accreditation requires evidence of continued compliance on an annual basis in order to maintain current accredited status.

Standard TCRX7-B: Organizations that are PCAB accredited for Sterile Compounding are required to provide documentation as evidence of compliance on an annual basis. This documentation is submitted two months prior to the anniversary of PCAB Accreditation.

Pharmacies must complete all forms provided in this packet and submit required documentation to ACHC. This packet must be completed for each accredited facility.

Steps:

1. ACHC will notify the pharmacy four months prior to the anniversary, providing the Continued Compliance packet.
2. Complete all forms contained within this packet using Adobe Reader:
   - CFST-1 Equipment Training/Competency
   - CFST-2 New Personnel Training
   - CFST-3 Ongoing Personnel Competency
   - CFST-4 Sterility and Endotoxin Summary Log
   - CFST-5 Equipment Calibration and Certification Summary
   - CFST-6 Quality Control Procedures
   - Additional Documentation
3. Pharmacy may submit packet via fax or email:
   - Fax completed packet and required documentation to 919-785-3011:
     - Complete and print fillable forms
     - Place documents in order following the corresponding form
     - Fax to the attention of Account Advisor
   - Email completed packet and required documentation to Account Advisor:
     - Save completed forms and required documentation into a folder with the name of your pharmacy
     - Compress file to reduce size
       - Right click folder > Send to compressed (zipped) folder
     - Attach compressed file to email with subject line "Continued Compliance – <<Pharmacy Name>>" and send to Account Advisor
4. Account Advisor will confirm receipt of documents and notify the pharmacy of any further action required.

Please contact your Account Advisor at 855-937-2242 with any questions.

Revised 12/1/14

CONTINUED COMPLIANCE
STERILE COMPOUNDING

Organization: _____ Date: _____

- How many of your employees perform sterile compounding at this location?
  - ☐ Full-time Pharmacists _____
  - ☐ Full-time Technicians _____
  - ☐ Part-time Pharmacists _____
  - ☐ Part-time Technicians _____
- Provide the following documentation regarding formulation records:
  - ☐ 10 random sterile compounding Master Formulation Records (MFRs):
    - » Submit a random sampling accross all the dosage forms compounded by the facility
  - ☐ The most recent (1) compounding record corresponding with each of the MFRs submitted
- Were there any Performance Improvement (PI) activities that did not meet acceptable standards in the last year?
  - ☐ No ☐ If yes, please provide the following:
    - » Written Plans of Correction (POCs) in response to any out-of-specification results
- Please provide the annual PI report:
  - ☐ Annual report may include but is not limited to the following:
    - » Name of designated person responsible for coordinating PI activities
    - » Summary and outcomes of PI activities performed in the last year
    - » Summary and outcomes of audit reports performed in the last year
    - » Summary and outcomes of patient feedback obtained in the last year
    - » Summary and outcomes of internal or external survey findings
    - » Summary and outcomes of quality control program for final preparations
    - » Summary and outcomes of any POCs developed in response to PI findings that did not meet threshold

EQUIPMENT TRAINING/ COMPETENCY

STERILE COMPOUNDING

ACHC | PCAB PHARMACY COMPOUNDING ACCREDITATION BOARD

Organization: _____ Date: _____

Was any sterile compounding equipment added at this location in the last year?

☐ No ☐ If yes, please provide the following for each new piece of equipment that was added:

- Completed Equipment Training /Competency summary including all employees that use the piece of equipment (use template below and create copies for additional equipment).
  - i. If personnel are in process of training, include projected dates of completion for any incomplete training
- Copy of training and competency assessment for each new piece of equipment:
  - i. This does not require individual employee documentation, ONLY a copy of the documentation used to perform the training and a blank competency assessment
  - ii. Competency assessment can be a didactic or observational audit AND must document standards for successful completion

Name of equipment: _____

EMPLOYEE INITIALS OR ID #	RPH OR TECHNICIAN	DATE TRAINING WAS / WILL BE COMPLETED	DATE COMPETENCY ASSESSMENT PERFORMED

NEW PERSONNEL TRAINING
STERILE COMPOUNDING

Organization: _____ Date: _____

New Sterile Personnel Initials or ID Number: _____

Were there any new sterile compounding personnel hired at this location in the last year?

☐ No ☐ If yes, please provide the following:

- Completed New Personnel Training summary for each new sterile compounding personnel (use template below and create copies for additional personnel).
    i. If personnel are in the process of training, include projected dates of completion for any incomplete training
- Copy of training and competency assessments that were completed by the new sterile compounding personnel:
    i. This does not require individual employee documentation, ONLY a copy of the documentation used to perform the training and a blank competency assessment
    ii. Competency assessment can be a didactic or observational audit AND must document standards for successful completion

TYPE OF TRAINING	DATE TRAINING WAS/WILL BE COMPLETED	DATE COMPETENCY ASSESSMENT WAS/WILL BE PERFORMED

ONGOING PERSONNEL COMPETENCY

STERILE COMPOUNDING

Organization: _____ Date: _____

Did facility perform any ongoing personnel competency for existing personnel in the last year?

☐ No ☐ If yes, please provide the following:

- Completed Ongoing Personnel Competency summary for all non-sterile compounding personnel (use template below and create copies if additional space is required).
- Copy of blank competency assessments that were completed by the sterile compounding personnel:
  - i. This does not require individual employee documentation, ONLY a copy of the documentation used to perform the training and the competency assessment
  - ii. Competency assessment can be a didactic or observational audit AND must document standards for successful completion

	EMPLOYEE #1		EMPLOYEE #2		EMPLOYEE #3	
	Employee Initials or ID #	Authorized Risk Level	Employee Initials or ID #	Authorized Risk Level	Employee Initials or ID #	Authorized Risk Level
COMPETENCY #1						
Date Assessment was Performed						
COMPETENCY #2						
Date Assessment was Performed						
COMPETENCY #3						
Date Assessment was Performed						
COMPETENCY #4						
Date Assessment was Performed						
COMPETENCY #5						
Date Assessment was Performed						
COMPETENCY #6						
Date Assessment was Performed						
COMPETENCY #7						

STERILITY AND ENDOTOXIN SUMMARY LOG

STERILE COMPOUNDING

ACHC | PCAB PHARMACY COMPOUNDING ACCREDITATION BOARD

Organization: _____ Date: _____

Did the facility perform any testing for sterility or endotoxins last year?

☐ No ☐ If yes, please provide the following for ONLY 10 preparations:

- Completed Sterility and Endotoxin Summary Log (use template below)
- Copy of third-party certificate of analysis for the preparations on the summary log
- Copy of plan(s) of corrections for any out of specification results obtained for the preparations on the summary log (if applicable)

PREPARATION NAME	LOT NUMBER	RISK LEVEL	NUMBER OF UNITS PREPARED/VOLUME PER UNIT	NUMBER OF UNITS TESTED	RESULTS OF STERILITY TEST (IF APPLICABLE)	RESULTS OF ENDOTOXIN TEST (IF APPLICABLE)

EQUIPMENT CALIBRATION AND CERTIFICATION SUMMARY

STERILE COMPOUNDING

Organization: _____ Date: _____

Was any sterile compounding equipment calibrated or certified in the past year, including: Biological Safety Cabinets (BSCs), laminar flow hoods, compounding isolators, scales, or thermometers?

☐ No ☐ If yes, please provide the following:

- Completed Equipment Calibration and Certification Summary for BSCs, laminar flow hoods, compounding isolators, scales, and thermometers ONLY (use template below):
  - i. This summary should ONLY include periodic calibrations and certifications; do not include daily activity in this summary.
- Daily balance calibration logs for ____ month(s) ONLY (state specific month in the blank, e.g., January):
  - i. The required month(s) will be provided to you by your Account Advisor
- Copy of all third-party calibration or certification documentation (if applicable).
- Copy of all facility-specific procedures used to calibrate or certify sterile lab compounding equipment, including standards for successful completion (if applicable).

EQUIPMENT NAME AND/OR ID#	WHO PERFORMED THE CALIBRATION OR CERTIFICATION	DATE OF COMPLETION

QUALITY CONTROL PROCEDURES

STERILE COMPOUNDING

Organization: _____ Date: _____

Did the facility perform any quality control procedures on finished preparations in the last year (eg., precision testing of automated compounding devices, potency testing, sterility testing, endotoxin testing, and visual inspections)?

☐ No ☐ If yes, please provide the following for ONLY 10 preparations:

- Completed Quality Control Procedures summary log (use template below)
- Copy of third-party quality control records for the preparations included in the summary log (e.g., potency certificates of analysis [if applicable])
- Copy of blank facility-specific procedures used to perform quality control procedures ONLY for the final preparations included in the summary log; be sure the procedure includes standards for successful completion (if applicable)

DESCRIPTION OF QUALITY CONTROL PROCEDURE	WHO PERFORMED THE PROCEDURE	DATE OF COMPLETION
EX: Potency Testing		

CONTINUED COMPLIANCE
NON-STERILE COMPOUNDING

PCAB Accreditation requires evidence of continued compliance on an annual basis in order to maintain current accredited status.

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 anniversary of PCAB Accreditation.

Pharmacies must complete all forms provided in this packet and submit required documentation to ACHC. This packet must be completed for each accredited facility.

Steps:

1. ACHC will notify the pharmacy four months prior to the anniversary, providing the Continued Compliance packet.
2. Complete all forms contained within this packet using Adobe Reader:
   - CFNS-1 Equipment Training/Competency
   - CFNS-2 New Personnel Training
   - CFNS-3 Ongoing Personnel Competency
   - CFNS-4 Equipment Calibration and Certification
   - CFNS-5 Quality Control Procedures
   - Additional Documentation
3. Pharmacy may submit packet via fax or email:
   - Fax completed packet and required documentation to 919-785-3011:
     - Complete and print fillable forms
     - Place documents in order following the corresponding form
     - Fax to the attention of Account Advisor
   - Email completed packet and required documentation to Account Advisor:
     - Save completed forms and required documentation into a folder with the name of your pharmacy
     - Compress file to reduce size
       - Right click folder > Send to compressed (zipped) folder
     - Attach compressed file to email with subject line "Continued Compliance – <<Pharmacy Name>>" and send to Account Advisor
4. Account Advisor will confirm receipt of documents and notify the pharmacy of any further action required.

Please contact your Account Advisor at 855-937-2242 with any questions.

Revised 12/1/14

CONTINUED COMPLIANCE
NON-STERILE COMPOUNDING

Organization: _____ Date: _____

- How many of your employees perform non-sterile compounding at this location?
  - ☐ Full-time Pharmacists _____
  - ☐ Full-time Technicians _____
  - ☐ Part-time Pharmacists _____
  - ☐ Part-time Technicians _____
- Provide the following documentation regarding formulation records:
  - ☐ 10 random non-sterile compounding Master Formulation Records (MFRs):
    - » Submit a random sampling across all the dosage forms compounded by the facility
  - ☐ The most recent (1) compounding record corresponding with each of the MFRs submitted
- Were there any Performance Improvement (PI) activities that did not meet acceptable standards in the last year?
  - ☐ No ☐ If yes, please provide the following:
    - » Written Plans of Correction (POCs) in response to any out-of-specification results
- Please provide the annual PI report:
  - ☐ Annual report may include but is not limited to the following:
    - » Name of designated person responsible for coordinating PI activities
    - » Summary and outcomes of PI activities performed in the last year
    - » Summary and outcomes of audit reports performed in the last year
    - » Summary and outcomes of patient feedback obtained in the last year
    - » Summary and outcomes of internal or external survey findings
    - » Summary and outcomes of quality control program for final preparations
    - » Summary and outcomes of any POCs developed in response to PI findings that did not meet threshold

EQUIPMENT TRAINING/ COMPETENCY

NON-STERILE COMPOUNDING

Organization: _____ Date: _____

Was any non-sterile compounding equipment added at this location in the last year?

☐ No ☐ If yes, please provide the following for each new piece of equipment that was added:

- Completed Equipment Training Competency Summary including all employees that use the piece of equipment (use template below and create copies for additional equipment).
    i. If personnel are in process of training, include projected dates of completion for any incomplete training
- Copy of training and competency assessment for each new piece of equipment:
    i. This does not require individual employee documentation, ONLY a copy of the documentation used to perform the training and a blank competency assessment
    ii. Competency assessment can be a didactic or observational audit AND must document standards for successful completion

Name of equipment: _____

EMPLOYEE INITIALS OR ID #	RPH OR TECHNICIAN	DATE TRAINING WAS / WILL BE COMPLETED	DATE COMPETENCY ASSESSMENT PERFORMED

NEW PERSONNEL TRAINING

NON-STERILE COMPOUNDING

Organization: _____ Date: _____

New Non-Sterile Personnel Initials or ID Number: _____

Were there any new non-sterile compounding personnel hired at this location in the last year?

☐ No ☐ If yes, please provide the following:

- Completed New Personnel Training summary for each new non-sterile compounding personnel (use template below and create copies for additional personnel).
    i. If personnel are in the process of training, include projected dates of completion for any incomplete training
- Copy of training and competency assessments that were completed by the new non-sterile compounding personnel:
    i. This does not require individual employee documentation, ONLY a copy of the documentation used to perform the training and a blank competency assessment
    ii. Competency assessment can be a didactic or observational audit AND must document standards for successful completion

TYPE OF TRAINING	DATE TRAINING WAS/WILL BE COMPLETED	DATE COMPETENCY ASSESSMENT WAS/WILL BE PERFORMED

ONGOING PERSONNEL COMPETENCY

NON-STERILE COMPOUNDING

Organization: _____ Date: _____

Did the facility perform any ongoing personnel competency for existing personnel in the last year?

☐ No ☐ If yes, please provide the following:

- Completed Ongoing Personnel Competency summary for all non-sterile compounding personnel (use template below and create copies if additional space is required).
- Copy of blank competency assessments that were completed by the non-sterile compounding personnel:
  - i. This does not require individual employee documentation, ONLY a copy of the documentation used to perform the training and the competency assessment
  - ii. Competency assessment can be a didactic or observational audit AND must document standards for successful completion

	EMPLOYEE #1		EMPLOYEE #2		EMPLOYEE #3	
	Employee Initials or ID #	Authorized Complexity	Employee Initials or ID #	Authorized Complexity	Employee Initials or ID #	Authorized Complexity
COMPETENCY #1						
Date Assessment was Performed						
COMPETENCY #2						
Date Assessment was Performed						
COMPETENCY #3						
Date Assessment was Performed						
COMPETENCY #4						
Date Assessment was Performed						
COMPETENCY #5						
Date Assessment was Performed						
COMPETENCY #6						
Date Assessment was Performed						
COMPETENCY #7						
Date Assessment was Performed						

EQUIPMENT CALIBRATION AND CERTIFICATION

NON-STERILE COMPOUNDING

Organization: _____ Date: _____

Was any non-sterile compounding equipment calibrated or certified in the past year, including: Class I Biological Safety Cabinets (BSCs) (powder hoods), scales, or thermometers?

☐ No ☐ If yes, please provide the following:

- Completed Equipment Calibration and Certification summary for Class I BSCs, scales, and thermometers ONLY (use template below):
  - i. This summary should ONLY include periodic calibrations and certifications; do not include daily activity in this summary
- Daily balance calibration logs for ____ month(s) ONLY (state specific month in the blank, e.g., January):
  - i. The month(s) will be provided to you by your Account Advisor
- Copy of all third-party calibration or certification documentation (if applicable)
- Copy of all facility-specific procedures used to calibrate or certify non-sterile lab compounding equipment, including standards for successful completion (if applicable)

EQUIPMENT NAME AND/OR ID#	WHO PERFORMED THE CALIBRATION OR CERTIFICATION	DATE OF COMPLETION

QUALITY CONTROL PROCEDURES

NON-STERILE COMPOUNDING

ACHC | PCAB PHARMACY COMPOUNDING ACCREDITATION BOARD

Organization: _____ Date: _____

Did the facility perform any quality control procedures on finished preparations in the last year?

☐ No ☐ If yes, please provide the following for ONLY 10 preparations:

- Completed Quality Control Procedures summary log (use template below)
- Copy of third-party quality control records for the preparations included in the summary log (e.g., potency certificates of analysis [if applicable])
- Copy of blank facility-specific procedures used to perform quality control procedures ONLY for the final preparations included in the summary log; be sure the procedure includes standards for successful completion (if applicable)

DESCRIPTION OF QUALITY CONTROL PROCEDURE	WHO PERFORMED THE PROCEDURE	DATE OF COMPLETION
EX: Weight assessments » Potency Testing		

AIS INSPECTION STANDARDS

[PHARMACY]

Customized for Sterile Compounding

AIS INSPECTION STANDARDS

Customized for ACHC Inspection Services

Section 10: ACHC Inspection Services (AIS)

ACHC Inspection Services (AIS) is a division of ACHC that provides inspection services for healthcare organizations seeking to fulfill pharmacy state licensure requirements. Committed to facilitating a higher level of quality and safety throughout the healthcare industry, AIS is made up of highly-qualified, industry-specific professionals who conduct thorough inspections on behalf of state regulatory bodies.

Standard AIS1-A: A pharmacy that is performing sterile compounding meets the following requirements for low-risk compounding.

Interpretation: Low-risk level Compounded Sterile Preparations (CSPs)

Does the pharmacy properly identify low-risk CSPs?

1. The CSPs are compounded with aseptic manipulations entirely within ISO Class 5 (particle count < 3520) or better air quality using only sterile ingredients, products, components, and devices.
2. The compounding involves only transfer, measuring, and mixing manipulations using not more than three commercially manufactured packages of sterile products and not more than two entries into any one sterile container or package (e.g., bag or vial) of sterile product or administration container/device to prepare the CSP.
3. Manipulations are limited to aseptically opening ampuls, penetrating disinfected stoppers on vials with sterile needles and syringes, and transferring sterile liquids in sterile syringes to sterile administration devices, package containers of other sterile products, and containers for storage and dispensing.

In the absence of passing a USP<71>-compliant sterility test are low-risk CSPs assigned the following Beyond-Use-Date (BUD): 48 hours at controlled room temperature, 14 days at cold temperature, or 45 days in solid frozen state between -25° and -10°?

Are appropriate media-fill tests completed annually for compounding personnel?

1. Media-fill test procedure: This test or an equivalent test is performed at least annually by each person authorized to compound in a low-risk level environment under conditions that closely simulate the most challenging or stressful conditions encountered during compounding of low-risk level CSPs. Once begun, this test is completed without interruption.
2. Test procedure example: Within an ISO Class 5 air quality environment, three sets of four 5-mL aliquots of sterile Soybean–Casein Digest Medium (also known as trypticase soy broth [TSB] or trypticase soy agar [TSA]) are transferred with the same sterile 10-mL syringe and vented needle combination into separate sealed, empty sterile 30-mL clear vials (i.e., four 5-mL aliquots into each of three 30-mL vials). Sterile adhesive seals are aseptically affixed to the rubber closures on the three filled vials, and then the vials are incubated at 20° to 25° or at 30° to 35° for a minimum of 14 days. If two temperatures are used to incubate media-filled samples, then these filled containers should be incubated for at least seven days at each temperature.

If Low-Risk CSPs with a 12-hour or less BUD are compounded, is required identification and compliance shown with all four criteria specified in USP<797>:

1. Primary Engineering Controls (PECs) are located in a segregated compounding area.
2. The segregated compounding area shall be away from windows, doors, and high traffic areas.
3. USP<797> gowning and garbing procedures are followed prior to compounding. Also, the sink is not adjacent to the PEC.
4. USP <797> specification s for cleaning and disinfecting, personnel training and competency evaluation of garbing, aseptic work practices and viable/non-viable environmental sampling apply.
    a. PECs (Laminar Airflow Workbenches [LAFWs], Biological Safety Cabinets [BSCs], Compounding Aseptic Isolators [CAIs] and Compounding Aseptic Containment Isolators [CACIs]) shall be certified and maintain ISO Class 5 as described in USP <797> - Facility Design and Environmental Controls for exposure of critical sites, and shall be in a segregated compounding area restricted to sterile compounding activities that minimize the risk of CSP contamination.
    b. The segregated compounding area shall not be in a location that has unsealed windows or doors that connect to the outdoors or high traffic flow, or that is adjacent to construction sites, warehouses, or food preparation. Note that this list is not intended to be all-inclusive.
    c. Personnel hall follow the procedures described in USP <797> - Personnel Cleansing and Garbing and Additional Personnel Requirements prior to compounding. Sinks should not be located adjacent to the ISO Class 5 PEC. Sinks should be separated from the immediate area of the ISO Class 5 PEC device.
    d. The specifications in USP <797> - Cleaning and Disinfecting the Sterile Compounding Areas, Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices and Cleaning/Disinfection Procedures, and Viable and Nonviable Environmental Sampling (ES) Testing shall be followed as described in the chapter.

Evidence: Observation
Evidence: Personnel Files

Services applicable: AIS

Standard AIS2-A: A pharmacy that is performing sterile compounding meets the following requirements for medium-risk compounding.

Interpretation: Medium-risk level CSPs

Does the pharmacy properly identify medium-risk CSPs?

1. Multiple individual or small doses of sterile products are combined or pooled to prepare a CSP that will be administered either to multiple patients or to one patient on multiple occasions.
2. The compounding process includes complex aseptic manipulations other than the single-volume transfer.
3. The compounding process requires an unusually long duration, such as that required to complete dissolution or homogeneous mixing.

In the absence of passing a USP<71>-compliant sterility test are medium-risk CSPs assigned the following BUD: 30 hours at controlled room temperature, 9 days at cold temperature, or 45 days in solid frozen state between -25° and -10°?

Are appropriate media-fill tests completed annually for compounding personnel?

1. Media-fill test procedure: This test or an equivalent test is performed at least annually under conditions that closely simulate the most challenging or stressful conditions encountered during compounding. Once begun, this test is completed without interruption.
2. Test procedure example: Within an ISO Class 5 air quality environment, six 100-mL aliquots of sterile Soybean–Casein Digest Medium are aseptically transferred by gravity through separate tubing sets into separate evacuated sterile containers. The six containers are then arranged as three pairs, and a sterile 10-mL syringe and 18-gauge needle combination is used to exchange two 5-mL aliquots of medium from one container to the other container in the pair.
3. For example, after a 5-mL aliquot from the first container is added to the second container in the pair, the second container is agitated for 10 seconds, and then a 5-mL aliquot is removed and returned to the first container in the pair. The first container is then agitated for 10 seconds, and the next 5-mL aliquot is transferred from it back to the second container in the pair. Following the two 5-mL aliquot exchanges in each pair of containers, a 5-mL aliquot of medium from each container is aseptically injected into a sealed, empty, sterile 10-mL clear vial, using a sterile 10-mL syringe and vented needle. Sterile adhesive seals are aseptically affixed to the rubber closures on the three filled vials, and then the vials are incubated at 20° to 25° or at 30° to 35° for a minimum of 14 days. If two temperatures are used to incubate media-filled samples, then these filled containers should be incubated for at least seven days at each temperature (see Microbiological Control and Monitoring of Aseptic Processing Environments <1116>). Inspect for microbial growth over 14 days as described in USP <797> - Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices and Cleaning/Disinfection Procedures.

Evidence: Observation
Evidence: Personnel Files

Services applicable: AIS

Standard AIS3-A: A pharmacy that is performing sterile compounding meets the following requirements for high-risk compounding.

Interpretation: High-Risk Level CSPs

Does the pharmacy properly identify high-risk CSPs?

1. Non-sterile ingredients, including manufactured products not intended for sterile routes of administration (e.g., oral), are incorporated or a non-sterile device is employed before terminal sterilization.
2. Any of the following are exposed to air quality worse than ISO Class 5 for more than one hour (see Immediate-Use CSPs):
    a. Sterile contents of commercially manufactured products
    b. CSPs that lack effective antimicrobial preservatives
    c. Sterile surfaces of devices and containers for the preparation, transfer, sterilization, and

packaging of CSPs

3. Compounding personnel are improperly garbed and gloved (see USP <797> - Personnel Cleansing and Use of Barrier Protective Equipment).
4. Non-sterile water-containing preparations are stored for more than six hours before being sterilized.
5. It is assumed, and not verified by examination of labeling and documentation from suppliers or by direct determination, that the chemical purity and content strength of ingredients meet their original or compendial specifications in unopened or in opened packages of bulk ingredients (see Ingredient Selection under Pharmaceutical Compounding—Non-sterile Preparations <795>).

In the absence of passing a USP<71>-compliant sterility test are high-risk CSPs assigned the following BUD: 24 hours at controlled room temperature, 3 days at cold temperature, or 45 days in solid frozen state between -25° and -10°?

Are appropriate media-fill tests completed semiannually for compounding personnel?

Media-Fill Test Procedure for CSPs Sterilized by Filtration—this test or an equivalent test is performed under conditions that closely simulate the most challenging or stressful conditions encountered when compounding high-risk level CSPs. Once begun, this test is completed without interruption.

Following is an example of a test procedure (in the following sequence):

1. Dissolve 3 g of non-sterile commercially available Soybean–Casein Digest Medium in 100 mL of non-bacteriostatic water to make a 3% non-sterile solution.
2. Draw 25 mL of the medium into each of three 30-mL sterile syringes. Transfer 5 mL from each syringe into separate sterile 10-mL vials. These vials are the positive controls to generate exponential microbial growth, which is indicated by visible turbidity upon incubation.
3. Under aseptic conditions and using aseptic techniques, affix a sterile 0.2-µm or 0.22-µm nominal pore size filter unit and a 20-gauge needle to each syringe. Inject the next 10 mL from each syringe into three separate 10-mL sterile vials. Repeat the process for three more vials. Label all vials, affix sterile adhesive seals to the closure of the nine vials, and incubate them at 20° to 25° or at 30° to 35° for a minimum of 14 days. If two temperatures are used for incubation of media-filled samples, then these filled containers should be incubated for at least 7 days at each temperature (see Microbiological Control and Monitoring of Aseptic Processing Environments ⟨1116⟩). Inspect for microbial growth over 14 days as described in USP <797> - Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices and Cleaning/Disinfection Procedures.

Are all non-sterile measuring, mixing, and purifying devices rinsed thoroughly with sterile, pyrogen-free water, and then thoroughly drained or dried immediately before use?

Are all high-risk level CSP solutions subjected to terminal sterilization pre-filtered by passing through a filter with a nominal pore size not larger than 1.2 µm preceding or during filling into their final containers to remove particulate matter?

Is sterilization of high-risk level CSPs by filtration performed with a sterile 0.2-µm or 0.22-µm nominal pore size filter entirely within an ISO Class 5 or superior air quality environment?

Evidence: Observation
Evidence: Personnel Files

Services applicable: AIS

Standard AIS4-A: A pharmacy that is performing sterile compounding meets the following requirements for personnel training and evaluation in aseptic manipulation skills.

Interpretation: Personnel Training and Evaluation in Aseptic Manipulation Skills

1. Are personnel who prepare CSPs trained by expert personnel and through audio–video instructional sources and professional publications in the theoretical principles and practical skills of aseptic manipulations and in achieving and maintaining ISO Class 5 environmental conditions before they begin to prepare CSPs?
2. Do compounding personnel perform a didactic review and pass written and media-fill testing of aseptic manipulative skills initially and at least annually thereafter for low- and medium-risk level compounding, and semiannually for high-risk level compounding?
    a. If compounding personnel fail written tests or if media-fill test vials result in gross microbial colonization, are they immediately re-instructed and re-evaluated by expert compounding personnel to ensure correction of all aseptic practice deficiencies?

Evidence: Observation
Evidence: Personnel Files

Services applicable: AIS

Standard AIS5-A: A pharmacy that is performing sterile compounding meets the following requirements for immediate-use CSPs.

Interpretation: Do immediate-use CSPs meet all six specific criteria to be exempt from requirements specified in low-risk level CSPs?

1. The compounding process involves the simple transfer of not more than three commercially manufactured packages of sterile nonhazardous products or diagnostic radiopharmaceutical products from the manufacturers' original containers and not more than two entries into any one container or package (e.g., bag or vial) of sterile infusion solution or administration container/ device. For example, anti-neoplastics shall not be prepared as immediate-use CSPs because they are hazardous drugs.
2. Unless required for the preparation, the compounding procedure is a continuous process not to exceed one hour.
3. During preparation, aseptic technique is followed and, if not immediately administered, the finished CSP is under continuous supervision to minimize the potential for contact with non-sterile surfaces, introduction of particulate matter or biological fluids, mix-ups with other CSPs, and direct contact of outside surfaces.
4. Administration begins not later than 1 hour following the start of the preparation of the CSP.
5. Unless immediately and completely administered by the person who prepared it or immediate and complete administration is witnessed by the preparer, the CSP shall bear a label listing patient identification information, the names and amounts of all ingredients, the name or initials of the person who prepared the CSP, and the exact 1-hour BUD and time.
6. If administration has not begun within 1 hour following the start of preparing the CSP, the CSP shall be promptly, properly, and safely discarded.

Evidence: Observation

Services applicable: AIS

Standard AIS6-A: A pharmacy that is performing sterile compounding meets the following requirements for single-dose and multiple containers.

Interpretation: Single-dose and Multiple Containers

1. Are opened or needle-punctured single-dose containers, such as bags, bottles, syringes, and vials of sterile products and CSPs used within one hour if opened in worse than ISO Class 5 air quality?
2. Are single-dose vials exposed to ISO Class 5 or cleaner air discarded within six hours of initial needle puncture?
3. Are single-dose ampules immediately discarded after use?
4. Are multiple-dose containers assigned a BUD of 28 days unless otherwise specified by the manufacturer?

Evidence: Observation

Services applicable: AIS

Standard AIS7-A: A pharmacy that is performing sterile compounding meets the following requirements for Hazardous Drug compounding.

Interpretation: Hazardous Drugs

1. Are hazardous drugs handled with caution at all times using appropriate chemotherapy gloves during receiving, distribution, stocking, inventorying, preparation for administration, and disposal?
2. Are hazardous drugs stored separately from other inventory in a manner to prevent contamination and personnel exposure?
3. Is access limited to areas where drugs are stored and prepared to protect persons not involved in drug preparation?
4. Are all hazardous drugs prepared in a BSC or a CACI that meets or exceeds the standards for CACI in USP<797>?
    a. The ISO Class 5 BSC or CACI shall be placed in an ISO Class 7 area that is physically separated (i.e., a different area from other preparation areas) and optimally has not less than 0.01-inch water column negative pressure to adjacent positive pressure ISO Class 7 or better ante-areas, thus providing inward airflow to contain any airborne drug. A pressure indicator shall be installed that can be readily monitored for correct room pressurization. The BSC and CACI optimally should be 100% vented to the outside air through High-Efficiency Particulate Air (HEPA) filtration. If a CACI that meets the requirements of this chapter is used outside of a buffer area, the compounding area shall maintain a minimum negative pressure of 0.01-inch water column and have a minimum of 12 air changes per hour (ACPHs). When closed-system vial-transfer devices (CSTDs) (i.e., vial-transfer systems that allow no venting or exposure of hazardous substances to the environment) are used, they shall be used within the ISO Class 5 environment of a BSC or CACI. The use of a CSTD is preferred because of their inherent closed

system process. In facilities that prepare a low volume of hazardous drugs, the use of two tiers of containment (e.g., CSTD within a BSC or CACI that is located in a non-negative pressure room) is acceptable.

5. Is a pressure indicator installed that can be readily monitored for correct room pressurization?
6. Is appropriate personnel protective equipment (PPE) worn when compounding in a BSC or CACI and when using CSTD devices?
    a. PPE may include gowns, face masks, eye protection, hair covers, shoe covers or dedicated shoes, double gloving with sterile chemo-type gloves, and compliance with manufacturers' recommendations when using a CACI.
7. Are all personnel who compound hazardous drugs trained initially and annually in the storage, handling, and disposal of these drugs?
    a. Verify documentation of initial and annual training per the following: training shall occur prior to preparing or handling hazardous CSPs, and its effectiveness shall be verified by testing specific hazardous drugs preparation techniques. Such verification shall be documented for each person at least annually.

    b. This training shall include:

    a. Didactic overview of hazardous drugs, including mutagenic, teratogenic, and carcinogenic properties, and shall include ongoing training for each new hazardous drug that enters the marketplace.

    b. At least the following: (1) safe aseptic manipulation practices (2) negative pressure techniques when utilizing a BSC or CACI (3) correct use of CSTD devices (4) containment, cleanup, and disposal procedures for breakages and spills and (5) treatment of personnel contact and inhalation exposure.
8. Have all compounding personnel of reproductive capability confirmed in writing that they understand the risks of handling hazardous drugs?
9. Does disposal of all hazardous drug wastes comply with all applicable federal and state regulations?
10. Do all personnel who perform routine custodial waste removal and cleaning activities in storage and preparation areas for hazardous drugs receive training in appropriate procedures to protect themselves and prevent contamination?

Evidence: Observation
Evidence: Personnel Files
Evidence: Response to Interviews

Services applicable: AIS

Standard AIS8-A: A pharmacy that is performing sterile compounding meets the following requirements for radiopharmaceuticals as CSPs.

Interpretation: Radiopharmaceuticals as CSPs

1. Are radiopharmaceuticals compounded using appropriately shielded vials and syringes in a properly functioning and certified ISO Class 5 PEC located in an ISO Class 8 or cleaner air environment to permit

compliance with special handling, shielding, and negative air flow requirements?

2. Are technetium-99m/molybdenum-99 generator systems stored and eluted (operated) under conditions recommended by manufacturers and applicable state and federal regulations?
    a. Are such generator systems eluted in an ISO Class 8 or cleaner air environment to permit special handling, shielding, and air flow requirements?
    b. Is direct visual inspection of radiopharmaceutical CSPs containing high concentrations of doses of radioactivity conducted at a level as reasonably achievable (ALARA)?
3. Are radiopharmaceuticals prepared as low-risk level CSPs with 12-hour or less BUD prepared in a segregated compounding area?
    a. Is a line of demarcation present, establishing the segregated compounding area?
    b. Are materials and garb exposed in patient care and treatment area prevented from crossing a line of demarcation into the segregated compounding area?

Evidence: Observation

Services applicable: AIS

Standard AIS9-A: A pharmacy that is performing sterile compounding meets the following requirements for allergen extracts as compounded sterile preparations (CSPs).

Interpretation: Allergen extracts as CSPs

If the pharmacy prepares allergen extracts, do they follow USP<797> requirements for CSPs, unless they meet the criteria for exemption?

Allergen extracts as compounded sterile preparations (CSPs) are subject to the personnel, environmental, and storage requirements for all CSP Microbial Contamination Risk Levels unless all of the following criteria are met:

1. The compounding process involves simple transfer via sterile needles and syringes of commercial sterile allergen products and appropriate sterile added substances (e.g., glycerin, phenol in sodium chloride injection).
2. All allergen extracts as CSPs shall contain appropriate substances in effective concentrations to prevent the growth of microorganisms. Non-preserved allergen extracts shall comply with the appropriate CSP risk level requirements in USP <797>.
3. Before beginning compounding activities, personnel perform a thorough hand-cleansing procedure by removing debris from under fingernails using a nail cleaner under running warm water followed by vigorous hand and arm washing to the elbows for at least 30 seconds with either non-antimicrobial or antimicrobial soap and water.
4. Compounding personnel don hair covers, facial hair covers, gowns, and face masks.
5. Compounding personnel perform antiseptic hand cleansing with an alcohol-based surgical hand scrub with persistent activity.
6. Compounding personnel don powder-free sterile gloves that are compatible with sterile 70% isopropyl alcohol (IPA) before beginning compounding manipulations.

7. Compounding personnel disinfect their gloves intermittently with sterile 70% IPA when preparing multiple allergens extracts as CSPs.
8. Ampul necks and vial stoppers on packages of manufactured sterile ingredients are disinfected by careful wiping with sterile 70% IPA swabs to ensure that the critical sites are wet for at least 10 seconds and allowed to dry before they are used to compound allergen extracts as CSPs.
9. The aseptic compounding manipulations minimize direct contact contamination (e.g., from glove fingertips, blood, nasal and oral secretions, shed skin and cosmetics, other non-sterile materials) of critical sites (e.g., needles, opened ampuls, vial stoppers).
10. The label of each multiple-dose vial (MDV) of allergen extracts as CSPs lists the name of one specific patient and a BUD and storage temperature range that is assigned based on manufacturers' recommendations or peer-reviewed publications.
11. Single-dose allergen extracts as CSPs shall not be stored for subsequent additional use.

Evidence: Observation

Services applicable: AIS

Standard AIS10-A: A pharmacy that is performing sterile compounding meets the following requirements for verification of compounding accuracy and sterility.

Interpretation: Verification of Compounding Accuracy and Sterility

1. Does the pharmacy have procedures to: review labels and document correct measurements, aseptic manipulations, and sterilization procedures to confirm correct identity, purity, and strength of ingredients in, and sterility of, CSPs?
2. Are sterilization methods verified to ensure sterility while maintaining strength, purity, quality and packaging integrity of the CSP?
    a. The selected sterilization process is obtained from experience and appropriate information sources (e.g., see Sterilization and Sterility Assurance of Compendial Articles ⟨1211⟩)—and, preferably, verified wherever possible—to achieve sterility in the particular CSPs. General guidelines for matching CSPs and components to appropriate sterilization methods include the following:

        i. CSPs have been ascertained to remain physically and chemically stable when subjected to the selected sterilization method.

        ii. Glass and metal devices may be covered tightly with aluminum foil, then exposed to dry heat in an oven at a mean temperature of 250° for 30 minutes to achieve sterility and depyrogenation (see Dry-Heat Sterilization under Sterilization and Sterility Assurance of Compendial Articles ⟨1211⟩ and Bacterial Endotoxins Test ⟨85⟩). Such items are either used immediately or stored until use in an environment suitable for compounding Low-Risk Level CSPs and Medium-Risk Level CSPs.

        iii. Personnel ascertain from appropriate information sources that the sterile microporous membrane filter used to sterilize CSP solutions, during either compounding or administration, is chemically and physically compatible with the CSP.

3. Sterilization Methods

a. For sterilization of high-risk CSPs by filtration:

i. Are filters used with a nominal porosity of 0.2-µm or 0.22-µm and certified by the manufacturer to retain at least (10to the power 7) microorganisms of a strain of Brevundimonas (Pseudomonas) diminuta on each square centimeter of upstream filter surface area under conditions similar to those in which the CSPs will be sterilized?

ii. Are filters sterile and pyrogen-free?

iii. Are filters approved for human-use in sterilizing pharmaceutical fluids?

iv. Is sterilization completed rapidly and without filter replacement?

v. Are filters subjected to manufacturers' recommended integrity test?

b. For sterilization of high-risk CSPs by steam:

i. Is the autoclave tested to verify the mass of containers to be sterilized will be sterile after the selected exposure duration?

ii. Is it ensured that live steam contacts all ingredients and surfaces to be sterilized?

iii. Are solutions passed through a 1.2-µm or smaller nominal pore size filter into final containers to remove particulates before sterilization?

iv. Is the effectiveness of steam sterilization verified using appropriate biological indicators and other confirmation methods such as temperature-sensing devices?

c. For sterilization of high-risk CSPs by dry heat:

i. Does the pharmacy only use dry heat for those materials that cannot be sterilized by steam, when the moisture would either damage or be impermeable to the materials?

ii. Is heated filtered air evenly distributed throughout the chamber by a blower device?

iii. Is sufficient space left between materials to allow for good circulation of hot air?

iv. Is the description of dry heat sterilization conditions and duration for specific CSPs included in written documentation in the compounding facility?

v. Is the effectiveness of dry heat sterilization verified using appropriate biological indicators and other confirmation methods such as temperature-sensing devices?

4. For depyrogenation by dry heat:

a. Is dry heat depyrogenation used to render glassware or containers such as vials free from pyrogens as well as viable microbes? A typical cycle would be 30 minutes at 250°.

b. Is the description of the dry heat depyrogenation cycle and duration for specific load items included in written documentation in the compounding facility?

c. Is the effectiveness of the dry heat depyrogenation cycle verified using endotoxin challenge vials (ECVs)?

Evidence: Written Policies and Procedures
Evidence: Observations

Services applicable: AIS

Standard AIS11-A: A pharmacy that is performing sterile compounding meets the following requirements for environmental quality and control.

Interpretation: Environmental Quality and Control

- Exposure of critical sites
  1. Are critical sites exposed to only ISO Class 5 or better air?
  2. Are critical sites protected by precluding direct contact contamination?

ISO Class 5 air sources, buffer areas, and ante-areas

1. Is the buffer area an area that provides at least ISO Class 7 air quality?
2. Does the compounding facility ensure that each source of an ISO Class 5 environment for exposure of critical sites and sterilization by filtration is properly located, operated, maintained, monitored, and verified?
3. Are devices (e.g., computers and printers) and objects (e.g., carts and cabinets) placed in buffer areas verified by testing or monitoring?

Evidence: Personnel Files
Evidence: Observation
Evidence: Written Policies and Procedures/Standard Operating Procedures

Services applicable: AIS

Standard AIS11-B: A pharmacy that is performing sterile compounding meets the following requirements for environmental quality and control.

Interpretation: Environmental Quality and Control

Facility Design and Environmental Controls

1. Are compounding facilities physically designed and environmentally controlled to minimize airborne contamination from contacting critical sites?
2. Do compounding facilities provide a comfortable and well-lighted working environment, which typically includes a temperature of 20° or cooler to maintain comfortable conditions for compounding personnel when attired in the required aseptic compounding garb?
3. Do PECs provide unidirectional (i.e., laminar) HEPA air at a velocity sufficient to prevent airborne particles from contacting critical sites?
4. Are in situ air pattern analysis via smoke studies conducted at the critical area to demonstrate unidirectional airflow and sweeping action over and away from the product under dynamic conditions?
5. Are policies and procedures for maintaining and working within the PEC area written and followed?
6. Are the principles of HEPA-filtered unidirectional airflow in the work environment understood and practiced in the compounding process in order to achieve the desired environmental conditions?
7. Are clean rooms for nonhazardous and nonradioactive CSPs supplied with HEPA that enters from ceilings with return vents low on walls, and that provides not less than 30 air changes per hour (ACPHs)?

8. Do buffer areas maintain 0.02- to 0.05-inch water column positive pressure, and do not contain sinks or drains?
9. Is air velocity from buffer rooms or zones to ante-areas at least 40 feet/minute?
10. Are PECs placed within a buffer area in such a manner as to avoid conditions that could adversely affect their operation?
11. Are the PECs placed out of the traffic flow and in a manner to avoid disruption from the HVAC system and room crossdrafts?
12. Is HEPA-filtered supply air introduced at the ceiling?
13. Are all HEPA filters efficiency tested using the most penetrating particle size and leak tested at the factory and then leak tested again in situ after installation?
14. Are activities and tasks carried out within the buffer area limited to only those necessary when working within a controlled environment?
15. Is only the furniture, equipment, supplies, and other material required for the compounding activities to be performed brought into the room?
16. Are surfaces and essential furniture in buffer rooms or zones and clean rooms nonporous, smooth, non-shedding, impermeable, cleanable, and resistant to disinfectants?
17. Are the surfaces of ceilings, walls, floors, fixtures, shelving, counters, and cabinets in the buffer area smooth, impervious, free from cracks and crevices, and non-shedding, thereby promoting cleanability, and minimizing spaces in which microorganisms and other contaminants may accumulate?
18. Are the surfaces resistant to damage by disinfectant agents?
19. Are junctures of ceilings to walls coved or caulked to avoid cracks and crevices where dirt can accumulate?
20. Are ceiling tiles caulked around each perimeter to seal them to the support frame?
21. Is the exterior lens surface of ceiling lighting fixtures smooth, mounted flush, and sealed?
22. Are any other penetrations through the ceiling or walls sealed?
23. Does the buffer area not contain sources of water (sinks) or floor drains?
24. Are work surfaces constructed of smooth, impervious materials, such as stainless steel or molded plastic, so that they are easily cleaned and disinfected?
25. Are carts composed of stainless steel wire, nonporous plastic, or sheet metal construction with good quality, cleanable casters to promote mobility?
26. Is storage shelving, counters, and cabinets smooth, impervious, free from cracks and crevices, nonshedding, cleanable, and disinfectable?
27. Do the number, design, and manner of installation of aforementioned items promote effective cleaning and disinfection?

Evidence: Observation
Evidence: Written Policies and Procedures

Services applicable: AIS

Standard AIS11-C: A pharmacy that is performing sterile compounding meets the following requirements for environmental quality and control.

Interpretation: Environmental Quality and Control

Placement of PECs

1. Are PECs for nonhazardous and nonradioactive CSPs located in buffer areas, except for CAIs that are proven to maintain ISO Class 5 air when particle counts are sampled 6 to 12 inches upstream of critical site exposure areas during performance of normal inward and outward transfer of materials, and compounding manipulations when such CAIs are located in air quality worse than ISO Class 7?
2. Are presterilization procedures for high-risk level CSPs, such as weighing and mixing, completed in no worse than an ISO Class 8 environment?
3. Are PECs located out of traffic patterns and away from room air currents that could disrupt the intended airflow patterns?
4. When isolators are used for sterile compounding, is the recovery time to achieve ISO Class 5 air quality documented and internal procedures developed to ensure that adequate recovery time is allowed after material transfer before and during compounding operations?

Evidence: Observation

Services applicable: AIS

Standard AIS11-D: A pharmacy that is performing sterile compounding meets the following requirements for environmental quality and control.

Interpretation: Environmental Quality and Control

Additional Personnel Requirements

1. When compounding activities require the manipulation of a patient's blood-derived or other biological material (e.g., radiolabeling a patient's or a donor's white blood cells), are the manipulations clearly separated from routine material-handling procedures and equipment used in CSP preparation activities, and controlled by specific standard operating procedures in order to avoid any cross-contamination?
2. Are food, drinks, and items exposed in patient care areas, and unpacking of bulk supplies and personnel cleansing and garbing prohibited from critical sites, buffer areas, ante-areas, and segregated compounding areas?
3. Is there a demarcation designation between buffer areas or rooms and ante-areas?

Evidence: Observation

Services applicable: AIS

Standard AIS11-E: A pharmacy that is performing sterile compounding meets the following requirements for environmental quality and control.

Interpretation: Environmental Quality and Control

Viable and Nonviable Environmental Sampling

1. Nonviable Sampling
    a. Is certification and testing of primary (LAFWs, BSCs, CAIs and CACIs) and secondary engineering controls (buffer and ante areas) performed by a qualified individual no less than every six months and whenever the device or room is relocated, altered, or major service to the facility is performed? Certification procedures such as those outlined in the CETA Certification Guide for Sterile Compounding Facilities (CAG-003-2006) shall be used.
    b. Are total particle counts in each ISO classified area within established guidelines? ISO Class 5: not more than 3520 particles 0.5 µm and larger size per cubic meter of air for any LAFW, BSC, CAI, and CACI; • ISO Class 7: not more than 352,000 particles of 0.5 µm size and larger per cubic meter of air for any buffer area; • ISO Class 8: not more than 3,520,000 particles or 0.5 µm size and larger per cubic meter of air for any ante-area.
    c. Are all certification records maintained and reviewed by supervising personnel or other designated employee to ensure that the controlled environments comply with the proper air cleanliness, room pressures, and ACPHs?

2. Pressure Differential Monitoring
    a. Is a pressure gauge or velocity meter installed to monitor the pressure differential or airflow between the buffer area and ante-area, and the ante-area and the general environment outside the compounding area?
    b. Are the results reviewed and documented on a log at least every work shift (minimum frequency shall be at least daily) or by a continuous recording device?
    c. Is the pressure between the ISO Class 7 and general pharmacy area not less than 5 Pa (0.02 - inch water column)?
    d. In facilities where low- and medium-risk level CSPs are prepared, does differential airflow maintain a minimum velocity of 0.2 meter/second (40 fpm) between buffer area and ante-area?

3. Viable Airborne Particle Testing Program
    a. Is an appropriate environmental sampling plan developed for airborne viable particles based on a risk assessment of compounding activities performed? Selected sampling sites shall include locations within each ISO Class 5 environment and in the ISO Class 7 and 8 areas, and the segregated compounding areas at greatest risk of contamination (e.g., work areas near the ISO Class 5 environment, counters near doors, and pass-through boxes). The plan shall include sample location, method of collection, frequency of sampling, volume of air sampled, and time of day as related to activity in the compounding area and action levels.
    b. Are proper growth media used? A general microbiological growth medium such as Soybean–Casein Digest Medium (also known as trypticase soy broth (TSB) or agar (TSA)) shall be used to support the growth of bacteria. Malt extract agar (MEA) or some other media that supports the growth of fungi shall be used in high-risk level compounding environments. Media used for surface sampling shall be supplemented with additives to neutralize the effects of disinfecting agents (e.g., TSA with lecithin and polysorbate 80).

c. Is evaluation of airborne microorganisms using volumetric collection methods in the controlled air environments performed by properly trained individuals for all compounding risk levels? Impaction shall be the preferred method of volumetric air sampling. For low-, medium-, and high-risk level compounding, air sampling shall be performed at locations that are prone to contamination during compounding activities and during other activities like staging, labeling, gowning, and cleaning. Locations shall include zones of air backwash turbulence within the LAFW and other areas where air backwash turbulence may enter the compounding area. For low-risk level CSPs with 12-hour or less BUD, air sampling shall be performed at locations inside the ISO Class 5 environment and other areas that are in close proximity to the ISO class 5 environment, during the certification of the primary engineering control.

d. Are the instructions in the manufacturer's user manual followed for verification and use of electric air samplers that actively collect volumes of air for evaluation?

e. Is a sufficient volume of air (400–1000 liters) tested at each location in order to maximize sensitivity?

f. Is air sampling performed at least semiannually (i.e. every six months), as part of the re-certification of facilities and equipment for areas where PECs are located?

g. Are the microbial growth media plates used to collect environmental sampling recovered, covers secured (e.g., taped), inverted, and incubated at a temperature and for a time period conducive to multiplication of microorganisms? TSA should be incubated at 35° ± 2 ° for 2–3 days. MEA or other suitable fungal media should be incubated at 28° ± 2 ° for 5–7 days.

h. Are the number of discrete colonies of microorganisms counted and reported as colony-forming units (cfus) and documented on an environmental monitoring form? Counts from air monitoring need to be transformed into cfu/cubic meter of air and evaluated for adverse trends.

i. Is sampling data collected and reviewed on a periodic basis as a means of evaluating the overall control of the compounding environment? Recommended Action Levels for Microbial Contamination: ISO Class 5 >1, ISO Class 7 >10, ISO Class 8 or worse >100. Regardless of the number of cfus identified in the compounding facility, further corrective actions will be dictated by the identification of microorganisms recovered (at least the genus level) by an appropriate credentialed laboratory of any microbial bioburden captured as a cfu using an impaction air sampler. If any mold, yeast, coagulase positive staphylococcus, or gram negative rods are detected immediate remediation and investigation into the cause and source is conducted.

j. Are competent microbiology personnel consulted if an environmental sampling consistently shows elevated levels of microbial growth?

k. Is an investigation into the source of the environmental contamination conducted?

Evidence: Observation

Services applicable: AIS

Standard AIS11-F: A pharmacy that is performing sterile compounding meets the following requirements for environmental quality and control.

Interpretation: Environmental Quality and Control

Cleaning and Disinfecting the Compounding Area

1. Do cleaning and disinfecting practices have written SOPs? SOPs should include: cleansers,

disinfectants, and non-shedding wipe and mop materials.

2. Are surfaces in the LAFWs, BSCs, CAIs, and CACIs cleaned and disinfected frequently, including at the beginning of each work shift, before each batch preparation is started, every 30 minutes during continuous compounding periods of individual CSPs, when there are spills, and when surface contamination is known or suspected from procedural breaches?
3. Are compounding personnel responsible for developing, implementing, and practicing the procedures for cleaning and disinfecting the DCAs written in the SOPs?
4. Does cleaning and disinfecting occur before compounding is performed? Items shall be removed from all areas to be cleaned, and surfaces shall be cleaned by removing loose material and residue from spills (e.g., water-soluble solid residues are removed with Sterile Water [for Injection or Irrigation] and low-shedding wipes). This shall be followed by wiping with a residue-free disinfecting agent, such as sterile 70% IPA, which is allowed to dry before compounding begins.
5. Are work surfaces in ISO Class 7 and 8 areas and segregated compounding areas cleaned at least daily?
6. Is dust and debris removed when necessary from storage sites for compounding ingredients and supplies, using a method that does not degrade the ISO Class 7 or 8 air quality?
7. Are floors in ISO Class 7 and 8 areas are cleaned daily when no compounding occurs?
8. Does IPA (70% isopropyl alcohol) remain on surfaces to be disinfected for at least 30 seconds before such surfaces are used to prepare CSPs?
9. Are emptied shelving, walls, and ceilings in ante-areas cleaned and disinfected at least monthly?
10. Is mopping performed by trained personnel using approved agents and procedures described in the written SOPs?
11. Are cleaning and disinfecting agents, their schedules of use, and methods of application in accordance with written SOPs and followed by custodial and/or compounding personnel?
12. Are all cleaning materials, such as wipers, sponges, and mops, nonshedding, preferably composed of synthetic micro fibers, and dedicated to use in the buffer area, ante-area, and segregated compounding areas and not to be removed from these areas except for disposal?
13. If cleaning materials are reused (e.g., mops), are procedures developed (based on manufacturer recommendations) that ensure that the effectiveness of the cleaning device is maintained and repeated use does not add to the bioburden of the area being cleaned?
14. Are supplies and equipment removed from shipping cartons and wiped with a suitable disinfecting agent (e.g., sterile 70% IPA) delivered from a spray bottle or other suitable delivery method?
15. After the disinfectant is sprayed or wiped on a surface to be disinfected, is the disinfectant allowed to dry, and during this is the item not used for compounding purposes?
16. Verify compliance - sterile 70% IPA wetted gauze pads or other particle-generating material shall not be used to disinfect the sterile entry points of packages and devices.

Evidence: Observation
Evidence: Written Policies and Procedures

Services applicable: AIS

Standard AIS11-G: A pharmacy that is performing sterile compounding meets the following requirements for environmental quality and control.

Interpretation: Environmental Quality and Control

Personnel Cleaning and Garbing

1. Are personnel thoroughly competent and highly motivated to perform flawless aseptic manipulations with ingredients, devices, and components of CSPs?
2. Are personnel with rashes, sunburn, weeping sores, conjunctivitis, active respiratory infection, and cosmetics prohibited from preparing CSPs?
3. Do compounding personnel remove personal outer garments; cosmetics; artificial nails; hand, wrist, and body jewelry that can interfere with the fit of gowns and gloves; and visible body piercing above the neck?
4. Does the order of compounding garb and cleansing in ante-area align with the following: shoes or shoe covers, head and facial hair covers, face mask, fingernail cleansing, hand and forearm washing and drying; non-shedding gown?
5. Does the order of cleansing and gloving in buffer room or area align with the following: hand cleansing with a persistently active alcohol-based product with persistent activity; allow hands to dry; don sterile gloves?
6. Are gloves routinely disinfected with sterile 70% IPA after contacting nonsterile objects?
7. Are gloves inspected for holes and replaced when breaches are detected?
8. Do personnel repeat proper procedures after they are exposed to direct contact contamination or worse than ISO Class 8 air?
9. Does the pharmacy employ the statement from USP<797> - " These requirements are exempted only for immediate-use CSPs and CAIs for which manufacturers provide written documentation based on validated testing that such personnel practices are not required to maintain sterility in CSPs."?

Evidence: Observation

Services applicable: AIS

Standard AIS11-H: A pharmacy that is performing sterile compounding meets the following requirements for environmental quality and control.

Interpretation: Environmental Quality and Control

Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices, and Cleaning/Disinfection Procedures

1. Are personnel who prepare CSPs trained conscientiously and skillfully by expert personnel, multi-media instructional sources, and professional publications in the theoretical principles and practical skills of garbing procedures, aseptic work practices, achieving and maintaining ISO Class 5 environmental conditions, and cleaning and disinfection procedures?
2. Is this training completed and documented before any compounding personnel begin to prepare CSPs?
3. Do compounding personnel complete didactic training, pass written competence assessments, undergo skill assessment using observational audit tools, and media-fill testing?
4. Is media-fill testing of aseptic work skills performed initially before beginning to prepare CSPs and at least annually thereafter for low- and medium-risk level compounding, and semiannually for high-risk level compounding?

5. Are compounding personnel who fail written tests, observational audits, or whose media-fill test vials have one or more units showing visible microbial contamination, reinstructed and re-evaluated by expert compounding personnel to ensure correction of all aseptic work practice deficiencies?
6. Do compounding personnel pass all evaluations prior to resuming compounding of sterile preparations?
7. Do compounding personnel demonstrate proficiency of proper hand hygiene, garbing, and consistent cleaning procedures in addition to didactic evaluation and aseptic media fill?
8. Are support personnel that perform cleaning and disinfecting procedures thoroughly trained in proper hand hygiene, and garbing, cleaning, and disinfection procedures by a qualified aseptic compounding expert?
9. Do support personnel routinely undergo performance evaluation of proper hand hygiene, garbing, and all applicable cleaning and disinfecting procedures conducted by a qualified aseptic compounding expert?
10. Are compounding personnel evaluated initially prior to beginning compounding CSPs and whenever an aseptic media fill is performed using forms such as Sample Form for Assessing Hand Hygiene and Garbing Related Practices of Compounding Personnel and the personnel glove fingertip sampling procedures?
11. Do all personnel demonstrate competency in proper hand hygiene and garbing procedures in addition to aseptic work practices?
12. Is monitoring of compounding personnel glove fingertips performed for all CSP risk level compounding?
13. Is glove fingertip sampling used to evaluate the competency of personnel in performing hand hygiene and garbing procedures in addition to educating compounding personnel on proper work practices? — All compounding personnel shall successfully complete an initial competency evaluation and gloved fingertip/thumb sampling procedure (zero cfu) no less than three times before initially being allowed to compound CSPs for human use. Immediately after the compounding employee completes the hand hygiene and garbing procedure (e.g., donning of sterile gloves prior to any disinfection with sterile 70% IPA), the evaluator will collect a gloved fingertip and thumb sample from both hands of the compounding employee onto appropriate agar plates by lightly pressing each fingertip into the agar. The plates will be incubated for the appropriate incubation period and at the appropriate temperature (see Incubation Period). After completing the initial gowning and gloving competency evaluation, re-evaluation of all compounding personnel for this competency shall occur at least annually for personnel who compound low- and medium-risk level CSPs and semi-annually for personnel who compound high-risk level CSPs using one or more sample collections during any media-fill test procedure before they are allowed to continue compounding CSPs for human use. Immediately prior to sampling, gloves shall not be disinfected with sterile 70% IPA. Disinfecting gloves immediately before sampling will provide false negative results. Plates filled with nutrient agar with neutralizing agents such as lecithin and polysorbate 80 added shall be used when sampling personnel fingertips. Personnel shall "touch" the agar with the fingertips of both hands in separate plates in a manner to create a slight impression in the agar. The sampled gloves shall be immediately discarded and proper hand hygiene performed after sampling. The nutrient agar plates shall be incubated as stated below (see Incubation Period). Results should be reported separately as number of cfu per employee per hand (left and right hand). The cfu action level for gloved hands will be based on the total number of cfus on both gloves, not per hand.
14. Are sterile contact agar plates used to sample the gloved fingertips of compounding personnel after garbing to assess garbing competency and after completing the media-fill preparation?

15. Verify - Gloves shall not be disinfected with sterile 70% IPA immediately prior to sampling.
16. Garbing and Gloving Competency Evaluation:
    a. Are compounding personnel visually observed during the process of performing hand hygiene and garbing procedures?
    b. Is the visual observation documented on a form such as Sample Form for Assessing Hand Hygiene and Garbing Related Practices of Compounding Personnel and maintained to provide a permanent record of and long-term assessment of personnel competency?
17. Gloved Fingertip Sampling:
    a. Immediately after the compounder completes the hand hygiene and garbing procedure, does the evaluator collect a gloved fingertip and thumb sample from both hands of the compounder onto appropriate agar plates by lightly pressing each finger tip into the agar?
    b. Do all employees successfully complete an initial competency evaluation and gloved fingertip/thumb sampling procedure (zero cfu) no less than three times before initially being allowed to compound CSPs for human use?
    c. After completing the initial gowning and gloving competency evaluation, does re-evaluation of all compounding personnel occur at least annually for low- and medium-risk level CSPs and semiannually for high-risk level CSPs before being allowed to continue compounding CSPs?
    d. Verify - Gloves shall not be disinfected with sterile 70% IPA prior to testing.
    e. Are the sampled gloves immediately discarded and proper hand hygiene performed after sampling?
    f. Is the cfu action level for gloved hands based on the total number of cfu on both gloves and not per hand?
    g. At the end of the designated sampling period, are the agar plates recovered, covers secured, inverted, and incubated at a temperature and for a time period conducive to multiplication of microorganisms? Trypticase soy agar (TSA) with lecithin and polysorbate 80 shall be incubated at 35°± 2° for 2–3 days.
18. Aseptic Manipulation Competency Evaluation:
    a. Do all compounding personnel have their aseptic technique and related practice competency evaluated initially during the media-fill test procedure and subsequent annual or semiannual media-fill test procedures on the Sample Form for Assessing Aseptic Technique and Related Practices of Compounding Personnel or equivalent form?
    b. Is the skill of personnel to aseptically prepare CSPs evaluated using sterile fluid bacterial culture media-fill verification?
    c. Are media-filled vials incubated within a range of 35° ± 2° for 14 days?
19. Surface Cleaning and Disinfection Sampling and Assessment:
    a. Is surface sampling performed in all ISO classified areas on a periodic basis, accomplished using contact plates and/or swabs, and done at the conclusion of compounding?
    b. Are locations to be sampled defined in a sample plan or on a form?
20. Cleaning and Disinfecting Competency Evaluation:
    a. Are compounding personnel and other personnel responsible for cleaning visually observed during

the process of performing cleaning and disinfecting procedures during initial personnel training on cleaning procedures, changes in cleaning staff, and at the completion of any media-fill test procedure?

b. Is visual observation documented on a form such as Sample Form for Assessing Cleaning and Disinfection Procedures and maintained to provide a permanent record of, and long-term assessment of, personnel competency?

21. Surface Collection Methods:

a. Immediately after sampling a surface with the contact plate, is the sampled area thoroughly wiped with a non-shedding wipe soaked in sterile 70% IPA?

22. Action Levels, Documentation, and Data Evaluation:

a. Is environmental sampling data collected and reviewed on a routine basis as a means of evaluating the overall control of the compounding environment?

b. If an activity consistently shows elevated levels of microbial growth, are competent microbiology personnel consulted?

c. Is an investigation into the source of the contamination conducted?

d. When gloved fingertip sample results exceed action levels after proper incubation, is a review of hand hygiene and garbing procedures as well as glove and surface disinfection procedures and work practices performed and documented? Recommended action levels for microbial contamination are as follows: Fingertip Sample: ISO Class 5 > 3. Surface Sample: ISO Class 5 > 3, ISO Class 7 > 5, ISO Class 8 or worse > 100

Evidence: Observation
Evidence: Personnel Files

Services applicable: AIS

Standard AIS12-A: A pharmacy that is performing sterile compounding has written policies and procedures and/or Standard Operating Procedures (SOPs).

Interpretation: Suggested Standard Operating Procedures

Does the pharmacy have SOPs designed to meet the following recommendations:

1. Access to the buffer area is restricted to qualified personnel with specific responsibilities or assigned tasks in the compounding area.
2. All cartoned supplies are decontaminated in the area by removing them from shipping cartons and wiping or spraying them with a nonresidue-generating disinfecting agent while they are being transferred to a clean and properly disinfected cart or other conveyance for introduction into the buffer area. Manufacturers' directions or published data for minimum contact time will be followed. Individual pouched sterile supplies need not be wiped because the pouches can be removed as these sterile supplies are introduced into the buffer area.
3. Supplies that are required frequently or otherwise needed close at hand but not necessarily needed for the scheduled operations of the shift are decontaminated and stored on shelving in the ante-area.

4. Carts used to bring supplies from the storeroom cannot be rolled beyond the demarcation line in the ante-area, and carts used in the buffer area cannot be rolled outward beyond the demarcation line unless cleaned and disinfected before returning.
5. Generally, supplies required for the scheduled operations of the shift are wiped down with an appropriate disinfecting agent and brought into the buffer area, preferably on one or more movable carts. Supplies that are required for backup or general support of operations may be stored on the designated shelving in the buffer area, but excessive amounts of supplies are to be avoided.
6. Nonessential objects that shed particles shall not be brought into the buffer area, including pencils, cardboard cartons, paper towels, and cotton items (e.g., gauze pads).
7. Essential paper-related products (e.g., paper syringe overwraps, work records contained in a protective sleeve) shall be wiped down with an appropriate disinfecting agent prior to being brought into the buffer area.
8. Traffic flow in and out of the buffer area shall be minimized.
9. Personnel preparing to enter the buffer area shall remove all personal outer garments, cosmetics (because they shed flakes and particles), and all hand, wrist, and other visible jewelry or piercings that can interfere with the effectiveness of PPE.
10. Personnel entering the ante-area shall don attire as described in Personnel Cleansing and Garbing and Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices and Cleaning/Disinfection Procedures.
11. Personnel shall then thoroughly wash hands and forearms to the elbow with soap and water for at least 30 seconds. An air dryer or disposable nonshedding towels are used to dry hands and forearms after washing.
12. Personnel entering the buffer area shall perform antiseptic hand cleansing prior to donning sterile gloves using a waterless alcohol-based surgical hand scrub with persistent activity.
13. Chewing gum, drinks, candy, or food items shall not be brought into the buffer area or ante-area. Materials exposed in patient care and treatment areas shall never be introduced into areas where components and ingredients for CSPs are present.
14. At the beginning of each compounding activity session, and whenever liquids are spilled, the surfaces of the direct compounding environment are first cleaned with USP Purified Water to remove water-soluble residues. Immediately thereafter, the same surfaces are disinfected with a nonresidue-generating agent using a nonlinting wipe.
15. Primary engineering controls shall be operated continuously during compounding activity. When the blower is turned off and before other personnel enter to perform compounding activities, only one person shall enter the buffer area for the purposes of turning on the blower (for at least 30 minutes) and disinfecting the work surfaces.
16. Traffic in the area of the direct compounding area (DCA) is minimized and controlled.
17. Supplies used in the DCA for the planned procedures are accumulated and then decontaminated by wiping or spraying the outer surface with sterile 70% isopropyl alcohol (IPA) or removing the outer wrap at the edge of the DCA as the item is introduced into the aseptic work area.
18. All supply items are arranged in the DCA to reduce clutter and provide maximum efficiency and order for the flow of work.
19. After proper introduction into the DCA of supply items required for and limited to the assigned operations, they are arranged so that a clear, uninterrupted path of HEPA-filtered air will bathe all critical sites at all times during the planned procedures. That is, no objects may be placed between the

first air from HEPA filters and an exposed critical site.

20. All procedures are performed in a manner designed to minimize the risk of touch contamination. Gloves are disinfected with adequate frequency with an approved disinfectant such as sterile 70% IPA.
21. All rubber stoppers of vials and bottles and the necks of ampuls are disinfected by wiping with sterile 70% IPA and waiting for at least 10 seconds before they are used to prepare CSPs.
22. After the preparation of every CSP, the contents of the container are thoroughly mixed and then inspected for the presence of particulate matter, evidence of incompatibility, or other defects.
23. After procedures are completed, used syringes, bottles, vials, and other supplies are removed, but with a minimum of exit and re-entry into the DCA so as to minimize the risk of introducing contamination into the aseptic workspace.

Evidence: Written Policies and Procedures/Standard Operating Procedures (SOP)

Services applicable: AIS

Standard AIS13-A: A pharmacy that is performing sterile compounding meets the following requirements for finished preparation checks and tests.

Interpretation: Finished preparation checks and tests

1. Are procedures and documents reviewed to ensure sterility, purity, correct identities and amounts of ingredients, and stability?
2. Are compounds visually inspected for abnormal particulate matter and color, and intact containers and seals?
3. Are high-risk level CSPs prepared in batches of more than 25 identical containers, or exposed longer than 12 hours at 2° to 8°, and 6 hours at warmer than 8° before being sterilized tested for sterility?
4. Are high-risk level CSPs, excluding those for inhalation and ophthalmic administration, prepared in batches of more than 25 identical containers, or exposed longer than 12 hours at 2° to 8°, and 6 hours at warmer than 8°, before being sterilized tested for bacterial endotoxin?
5. Are there written procedures to verify correct identity, quality, amounts, and purities of ingredients used in CSPs?
6. Are there written procedures to ensure labels of CSPs contain correct names and amounts or concentrations of ingredients, total volumes, BUDs, storage conditions, and route(s) of administration?

Evidence: Written Policies and Procedures/Standard Operating Procedure (SOP)
Evidence: Observation

Services applicable: AIS

AIS INSPECTION STANDARDS

Standard AIS14-A: A pharmacy that is performing sterile compounding meets the following requirements for storage and Beyond-Use-Date (BUD).

Interpretation: Storage and BUD

In determining BUDs does the pharmacy use the general criteria USP <795> in the absence of direct stability-indicating assays or authoritative literature that supports longer durations?

BUDs should be assigned conservatively. When assigning a BUD, compounders shall consult and apply drug-specific and general stability documentation and literature when available and should consider:

- The nature of the drug and its degradation mechanism
- The dosage form and its components
- The potential for microbial proliferation in the preparation
- The container in which it is packaged
- The expected storage conditions
- The intended duration of therapy

Evidence: Observation

Services applicable: AIS

Standard AIS15-A: A pharmacy that is performing sterile compounding meets the following requirements for maintaining sterility, purity, and stability of dispensed and CSPs.
Interpretation: Maintaining Sterility, Purity, and Stability of Dispensed CSPs

1. Are procedures written for proper packaging, storage, and transportation conditions to maintain sterility, quality, purity, and strength of CSPs?
2. Are CSPs only redispensed when sterility, and acceptable purity, strength, and quality can be ensured by personnel responsible for sterile compounding?
3. Is assignment of sterility storage times and stability BUDs that occur later than those of originally dispensed CSPs based on results of sterility testing and quantitative assay of ingredients?
4. Does packaging maintain physical integrity, sterility, stability, and purity of CSPs?
5. Do modes of transport maintain appropriate temperatures and prevent damage to CSPs?

Evidence: Written Policies and Procedures/Standard Operating Procedure (SOP)
Evidence: Observation

Services applicable: AIS

Standard AIS16-A: A pharmacy that is performing sterile compounding meets the following requirements for patient and/or caregiver training.

Interpretation: Patient or Caregiver Training

1. Does the pharmacy provide a multiple component formal training program to ensure that patients and caregivers understand the proper storage, handling, use, and disposal of CSPs?

Evidence: Training Program for Patients/Caregiver
Evidence: Observation

Services applicable: AIS

Standard AIS17-A: A pharmacy that is performing sterile compounding meets the following requirements for patient monitoring and adverse events reporting.

Interpretation: Patient monitoring and adverse events reports

1. Do written standard procedures describe means for patients to ask questions and report concerns and adverse events with CSPs, and for compounding supervisors to correct and prevent future problems?

Evidence: Written Policies and Procedures/Standard Operating Procedure (SOP)
Evidence: Observation

Services applicable: AIS

Standard AIS18-A: A pharmacy that is performing sterile compounding meets the following requirements for a quality assurance (QA) program.

Interpretation: Quality Assurance Program

1. Does the provider of CSPs have in place a formal QA program intended to provide a mechanism for monitoring, evaluating, correcting, and improving the activities and processes described in USP<797>?

Emphasis in the QA program is placed on maintaining and improving the quality of systems and the provision of patient care. In addition, the QA program ensures that any plan aimed at correcting identified problems also includes appropriate follow-up to make certain that effective corrective actions were performed. Characteristics of a QA program include the following:

- **a.** Formalization in writing
- **b.** Consideration of all aspects of the preparations and dispensing of products as described in this chapter, including environ- mental testing and verification results
- **c.** Description of specific monitoring and evaluation activities
- **d.** Specification of how results are to be reported and evaluated
- **e.** Identification of appropriate follow-up mechanisms when action limits or thresholds are exceeded
- **f.** Delineation of the individuals responsible for each aspect of the QA program; in developing a specific plan, focus is on establishing objective, measurable indicators for monitoring activities and processes that are deemed high-risk, high-volume, or problem-prone. In general, the selection of

indicators and the effectiveness of the overall QA program is reassessed on an annual basis.

Evidence: Quality Assurance Plan

Services applicable: AIS

Standard AIS19-A: A pharmacy that is performing sterile compounding meets the following requirements for USP <71> sterility tests.

Interpretation: USP<71> Sterility Tests

Are the number of articles tested appropriate according to USP<71>?

1. Minimum Quantity to be Used for Each Medium: Minimum Quantity to be Used and Quantity per Container (unless otherwise justified and authorized):
2. 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.
3. Insoluble preparations, creams, and ointments to be suspended or emulsified: Use the contents of each container to provide not less than 200 mg.
4. Solids: Less than 50 mg - the whole contents of each container; 50 mg or more, but less than 300 mg - half the contents of each container, but not less than 50 mg; 300 mg–5 g - 150 mg; Greater than 5 g - 500 mg.
5. Catgut and other surgical sutures for veterinary use 3 sections of a strand (each 30-cm long).
6. Surgical dressing/cotton/gauze (in packages): 100 mg per package.
7. Sutures and other individually packaged single-use material: The whole device.
8. Other medical devices: The whole device, cut into pieces or disassembled.

Is the volume/quantity tested is according to USP<71>?

1. Parenteral preparations: Not more than 100 containers - 10% or 4 containers, whichever is the greater; More than 100 but not more than 500 containers - 10 containers; More than 500 containers - 2% or 20 containers, whichever is less; For large-volume parenterals 2% or 10 containers, whichever is less (* If the batch size is unknown, use the maximum number of items prescribed).
2. Antibiotic solids: Pharmacy bulk packages (<5 g) - 20 containers; Pharmacy bulk packages (≥5 g) - 6 containers; Bulks and blends - See Bulk solid products.
3. Ophthalmic and other non-injectable preparations: Not more than 200 containers - 5% or 2 containers, whichever is the greater; More than 200 containers - 10 containers.
4. If the product is presented in the form of single-dose containers, apply the scheme shown above for preparations for parenteral use. If the batch size is unknown, use the maximum number of items prescribed.
5. Catgut and other surgical sutures for veterinary use: 2% or 5 packages, whichever is the greater, up to a maximum total of 20 packages; Not more than 100 articles - 10% or 4 articles, whichever is greater; More than 100, but not more than 500 articles - 10 articles;More than 500 articles - 2% or 20 articles, whichever is less.
6. 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.

Is membrane filtration used if appropriate?

1. (The technique of membrane filtration is used whenever the nature of the product permits; that is, for filterable aqueous preparations, for alcoholic or oily preparations, and for preparations miscible with, or soluble in, aqueous or oily solvents, provided these solvents do not have an antimicrobial effect in the conditions of the test.) Filters are rinsed according to USP<71

Is direct inoculation done only when membrane filtration cannot be carried out?

Is volume to be inoculated not more than 10% of the culture media volume?

Has a growth promotion test has been done on the media with the five specified organisms (not more than 100 colony forming units [cfus] according to USP<71>?

Has a USP<71> method suitability test been done with appropriate inoculum, additives and rinses?

Are samples in TSB or SCD incubated at 20-25°C for 14 days?

Are samples in FTM incubated at 30-35°C for 14 days?

Is Sterility testing documented including lot numbers and expiration dates of media?

Are sterility testing reports reviewed and appropriate actions taken and documented?

Evidence: Observation

Services applicable: AIS

Standard AIS20-A: A pharmacy that is performing sterile compounding meets the following requirements for USP <85> bacterial endotoxins testing.

Interpretation: USP<85> Bacterial Endotoxins Test

1. Do outsourced endotoxin testing results indicate that it is compliant with USP<85>?
2. Is USP<85> endotoxin testing done on site?
3. Is the endotoxin testing method compliant?
   a. Indicate: Gel clot, chromogenic or turbidimetric?
4. Are high-risk CSPs within allowable limits for bacterial endotoxins?

Evidence: Observations

Services applicable: AIS

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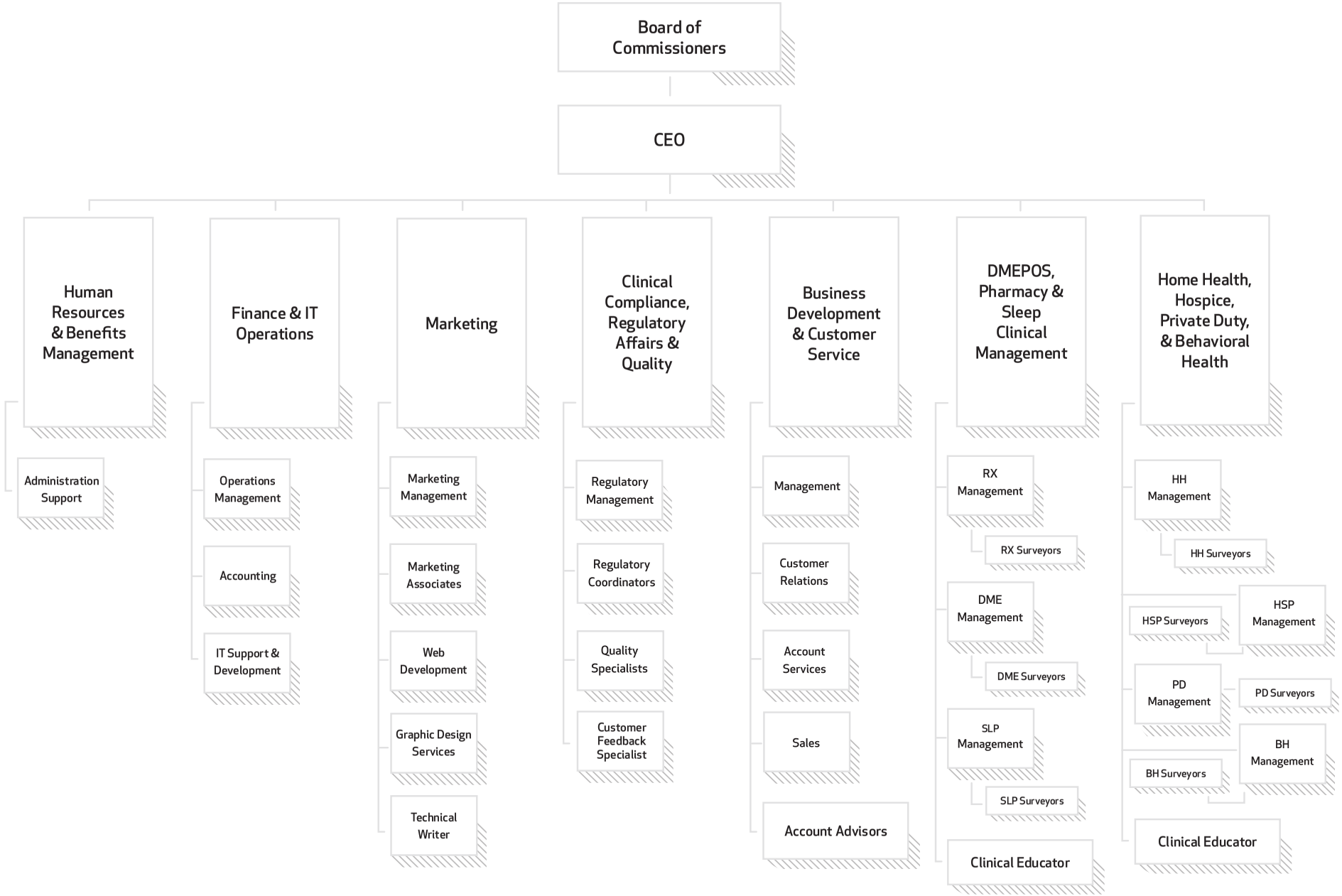
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