COMMONWEALTH OF VIRGINIA

Meeting of the Board of Pharmacy

Perimeter Center, 9960 Mayland Drive, Second Floor
Henrico, Virginia 23233

(804) 367-4456 (Tel)
(804) 527-4472(Fax)

Tentative Agenda of Ad Hoc Inspection Committee

June 4, 2014

2:30PM

TOPIC	PAGE(S)

Call to Order: Ellen Shinaberry, Chairman

- Welcome & Introductions
- Reading of Emergency Evacuation Script
- Approval of Agenda
- Background information:
  - Possible discussion topics — 1
  - Guidance Document 110-38 — 2
  - Guidance Document 110-36 — 3-11
  - Correspondence from National Home Infusion Association — 12-13
- Request from *LDT health solutions Pharmacy Consultants* to accept compounding assessment for either resident or nonresident pharmacies — 14-36
- Request from *Accreditation Commission for Health Care* to accept compounding certification for either resident or nonresident pharmacies — 37-116
- Adjournment

Board Action

- Consider requests from *LDT health solutions Pharmacy Consultants* and *Accreditation Commission for Health Care* to accept compounding assessment/certification for either resident or nonresident pharmacies.

Possible Discussion Topics

1. Is the assessment or certification for both sterile and non-sterile compounding?
2. What are the qualifications of the person performing the assessment?
3. What training has the person performing the assessment received?
4. Is the assessment for all applicable sections of USP-NF or solely chapters <795> and <797>?
5. Will the assessment of USP-NF standards be performed in a manner that is consistent with Guidance Document 110-36?
6. Are the assessments unannounced?
7. How often is an assessment performed?
8. What is the length of time for performing an assessment?
9. What type of information will be shared with the Board and within what timeframe?
10. What is the process for requiring and assessing corrective action? Is documentation of non-compliance shared with the Board? Will the corrective action be shared with the Board?
11. Does the assessment involve the completion of a self-assessment tool?
12. What entities currently hold certification with ACHC or have been assessed by LDT health solutions? Have these entities subsequently been disciplined by a state or federal regulatory agency?
13. What is the cost of the assessment or certification?
14. How quickly can the entity accommodate a request for an assessment?

Virginia Board of Pharmacy

Requirement for Non-resident Pharmacies to Submit Current Inspection Report

The Board of Pharmacy may issue a permit to a non-resident pharmacy that meets requirements of law and regulation, including the submission of an inspection report satisfactory to the Board. The law (Code of Virginia) provides:

§ 54.1-3434.1. Nonresident pharmacies to register with Board.

...

As a prerequisite to registering or renewing a registration with the Board, the nonresident pharmacy shall submit a copy of a current inspection report resulting from an inspection conducted by the regulatory or licensing agency of the jurisdiction in which it is located that indicates compliance with the requirements of this chapter, including compliance with USP-NF standards for pharmacies performing sterile and non-sterile compounding. The inspection report shall be deemed current for the purpose of this subdivision if the inspection was conducted (i) no more than six months prior to the date of submission of an application for registration with the Board or (ii) no more than two years prior to the date of submission of an application for renewal of a registration with the Board. However, if the nonresident pharmacy has not been inspected by the regulatory or licensing agency of the jurisdiction in which it is licensed within the required period, the Board may accept an inspection report or other documentation from another entity that is satisfactory to the Board or the Board may cause an inspection to be conducted by its duly authorized agent and may charge an inspection fee in an amount sufficient to cover the costs of the inspection.

...

For the purpose of compliance with the requirement for such a report, the Board offers the following guidance:

An application for registration or renewal without an inspection report that indicates compliance with the requirements of this chapter, including compliance with USP-NF standards for pharmacies performing sterile and non-sterile compounding, will be deemed incomplete and a registration will not be issued or renewed until such time as a report or other acceptable documentation is produced. Inspection reports from the National Association of Boards of Pharmacy (NABP) that satisfy the inspection report requirements of §54.1-3434.1 will be deemed acceptable alternatives to an inspection by the licensing or regulatory agency of jurisdiction or an inspection by the Board of Pharmacy's own agent.

Notwithstanding submission of an inspection report from a source acceptable to the Board, the Board may deny an application on the grounds that the applicant failed to comply with applicable laws or regulations. The applicant would have an opportunity for a hearing before a committee of the Board.

Virginia Board of Pharmacy

COMPLIANCE WITH USP STANDARDS FOR COMPOUNDING

§54.1-3410.2 requires pharmacies performing sterile or non-sterile compounding to comply with USP Standards. USP standards for sterile and non-sterile compounding may be found in the current editions of the USP-NF. In accordance with 18VAC110-20-170, the Board requires a pharmacy to maintain references consistent with the pharmacy's scope of practice and with public safety.

USP Chapter 795 lists the requirements for non-sterile compounding including information about the compounding environment, equipment, stability criteria and beyond-use dating and records. USP Chapter 797 lists requirements for policies and procedures, training and evaluation of personnel performing sterile compounding, determining risk levels and the physical standards for the sterile compounding area. The Board expects that the requirements of Chapters 795 and 797 will be found in compliance at time of inspection.

The terms "annually" and "semiannually" as used in USP Chapters 795 and 797 are defined to mean every 12 months and every 6 months, respectively. Records associated with annual and semiannual requirements shall be maintained in accordance with USP standards. Such records may be maintained as an electronic image that provides an exact image of the document that is clearly legible provided such electronic image is retrievable and made available at the time of inspection or audit by the Board or an authorized agent.

1. ***Where may information regarding USP-NF standards for compounding be located?***

   A subscription to the current version of "USP on Compounding: A Guide for the Compounding Practitioner" may be purchased at http://www.usp.org/store/products-services/usp-compounding This guide provides access to all compounding-related General Chapters from the USP-NF and is updated with the release of each new USP-NF edition and supplement. The latest edition, USP 36- NF 31, published on November 1, 2012 becomes official May 1, 2013.

2. ***Does the law require compliance only with Chapter <797>?***

   No, the law requires compliance with all applicable chapters within USP-NF. Regarding sterile compounding, pharmacists should pay particularly close attention to General Chapters: <1> Injections, <51> Antimicrobial Effectiveness Testing, <71> Sterility Testing, <85> Bacterial Endotoxin Testing, and <797> Pharmaceutical Compounding- Sterile Preparations.

3. ***In the absence of sterility testing, what beyond use dates (BUDs) must be used?***

   When sterility testing has not been performed, the assigned BUD must not exceed the following allowances:

	Controlled Room	Refrigerator	Freezer

	Temperature		
Low-risk	48 hours	14 days	45 days
Medium-risk	30 hours	9 days	45 days
High-risk	24 hours	3 days	45 days

4. ***Is it appropriate to assign a BUD of 90 days in the absence of sterility testing if there is literature indicating the stability of the drug is assured for 90 days?***
No, it is inappropriate and a violation of law to assign a BUD which exceeds the USP default BUDs in the absence of sterility testing. Drug stability should not be confused with drug sterility.

5. ***What is skip lot testing and may skip lot testing be used to perform sterility testing of compounded sterile products?***

Skip lot testing is a process that only tests a fraction of the drugs compounded. It is NOT appropriate for sterility testing. It may only be used for ensuring consistency and drug strength (potency). Because skip lot testing is complex and requires a robust program, it may not be possible for a pharmacy to properly implement. Information regarding skip lot testing may be accessed at http://www.itl.nist.gov/div898/handbook/pmc/section2/pmc27.htm

6. ***How may a hospital pharmacy "batch-producing" limited quantity of CSPs for IN-HOUSE use extend the BUD past the default dating in Chapter <797>?***

EACH BATCH must undergo sterility testing in accordance with USP Chapter <71> in order to extend the BUD past the default dating in Chapter <797> and the appropriate documentation to support an extended BUD must be kept on file for presentation upon inspection.

7. ***Do batches less than 25 require sterility testing to be performed?***

No, however, the batches may not be assigned a BUD which exceeds the default BUDs in USP Chapter <797>. The chapter requires sterility testing according to USP <71> before CSPs are dispensed or administered when:

- high-risk level CSPs that are prepared in groups of more than 25 identical individual single-dose packages (e.g., ampuls, bags, syringes, vials) or
- in multiple-dose vials (MDVs) for administration to multiple patients or
- CSPs that are exposed longer than 12 hours at 2 to 8 C and longer than 6 hours at warmer than 8 C before they are sterilized.

8. ***How often must the primary engineering control, e.g., laminar airflow workbench and secondary engineering control, e.g., ante and buffer rooms be certified?***

Certification of the primary and secondary engineering controls shall be performed no less than every six months and whenever the device or room is relocated, altered, or major service to the facility is performed. The certification must be performed no later than *the last day of the sixth month*, following the previous certification.
***Note- this guidance reflects a change to Major Deficiencies 22 and 23 in Guidance Document 110-9 which was amended at the March 2013 full board meeting.

9. ***Must compounding personnel who work in multiple pharmacies, to include pharmacy interns on rotations, pass a media-fill test at each pharmacy where they will prepare CSPs?***

Yes, all compounding personnel working in multiple pharmacies, to include pharmacy interns on rotations, must pass a media-fill test at each pharmacy prior to performing sterile compounding.

10. ***How often must media-fill testing be performed?***

Media-fill testing of all compounding personnel shall be performed initially prior to beginning sterile compounding and at least annually thereafter for low and medium-risk compounding, and semiannually for high-risk level compounding. ***Note** - the terms "annually" and "semi-annually" are defined within this guidance document to mean every 12 months and every 6 months, respectively.

11. ***If compounding personnel fail a media-fill test, may they continue preparing compounded sterile products?***

No, compounding personnel who failed a media-fill test may not be allowed to prepare compounded sterile products (low, medium, or high-risk) prior to retraining and receipt of a passing media-fill test. ***Note-** this guidance reflects a change to Major Deficiency 26a in Guidance Document 110-9 which was amended at the March 2013 full board meeting.

12. ***Because batches less than 25 do not require sterility testing to be performed, may the CSP which may have been autoclaved be assigned an extended BUD based on stability data?***

Yes, sterility tests for autoclaved CSPs are not required unless they are prepared in batches of more than 25 units. The board would expect to see that biological indicators are used with each autoclave batch and that the cycle time and temperature were recorded on a log or printer tape directly from the autoclave.

13. ***Does USP-NF address how long a CSP may hang for infusion?***
No, USP-NF does not address how long a CSP may hang for infusion. Refer to facility policy on this issue. USP-NF, however, does require the administration of CSPs to begin prior to the assigned BUD.

14. ***May a pharmacist repackage Avastin for office administration not pursuant to a patient-specific prescription?***

No. While pharmacists may repackage a drug product when dispensing a drug pursuant to patient-specific prescription, a pharmacist may not repackage a drug for another entity. The board has historically interpreted the repackaging of a drug for distribution purposes as an act restricted to a manufacturer, defined in Va Code §54.1-3401. This interpretation appears consistent with recent warning letters from the US Food and Drug Administration (FDA). The allowance in Va Code §54.1-3401 for a pharmacist to provide compounded drugs to a physician for office administration does not apply. Repackaging Avastin does not constitute compounding as it does not involve the mixing of two of more substances.

15. ***May a pharmacist repackage Avastin pursuant to a patient-specific prescription?***

Yes, a pharmacist may repackage a drug as part of the dispensing process pursuant to a patient-specific prescription.

16. What concepts, at a minimum, should be taken into consideration when performing sterility testing of CSPs?

- Maintain a written policy and procedure manual clearly identifying sterility testing procedures used by the pharmacy and processes for assigning BUDs.
- Prior to using an outside testing company to perform sterility testing, evaluate the company to determine if it performs testing in full compliance with USP Chapter <71>. This may be done by reviewing 483 reports issued by the FDA to the testing company and which may be available on the FDA website. Alternatively, request copies of the 483 reports directly from the testing company. The observed deficiencies noted on the 483 reports will assist the pharmacist in evaluating the testing company's level of compliance. Also, request written documentation from the testing company which explains the sterility testing processes used and how it complies with USP Chapter <71> in its totality. This documentation should contain, at a minimum, specific details regarding the method of testing, method suitability associated with each sterility testing process to ensure the drug being tested will not interfere with the test, identification of testing method (membrane filtration is the preferred method of testing), two growth media, and number of days of incubation. Have this documentation readily available for inspector review.
- When performing sterility testing in-house, document in the written policy and procedure manual, at a minimum, specific details regarding the method of testing, method suitability associated with each sterility testing process to ensure the drug being tested will not interfere with the test, identification of two growth media, and number of days of incubation.
- Vendors providing products for in-house testing must describe all conditions and limitations to their testing products. Ensure the appropriate filtration volume and sample size is being tested.
- When determining an appropriate sterility testing process, note that the preferred method per USP is membrane filtration. The Board strongly recommends that written documentation justifying the use of direct inoculation be available for inspection
- Ensure the sterility testing incorporates two media for growth.
- The sample size used for testing must comply with USP Chapter <71>, tables 2 and 3.
- Maintain robust recordkeeping, e.g., chart the dates, temperatures, growth associated with the two media incubations, and employee signatures. Do not simply indicate "no growth" without indicating which growth media was used and the number of days incubated.

17. Must sterility testing be performed on all batches of CSPs?

Sterility testing is not required of low and medium-risk level batched CSPs if the BUDs do not exceed the default BUDs found in USP Chapter <797>. If the low or medium-risk level batched CSP is to be assigned an extended BUD, then sterility testing must be performed. Sterility testing must always be performed of high-risk level CSPs in batches greater than 25. See Response to Q#7

18. What is the definition of a "batch"?

USP does not currently define the term "batch". In 21CFR210.3, FDA defines "batch" to mean a specific quantity of a drug or other material that is intended to have uniform character and quality, within specified limits, and is produced according to a single manufacturing order during the same cycle of manufacture.

19. *How should a dilution or stock bag for pediatrics be treated?*

USP does not currently address this issue, however, the Board advises that the dilution or stock bag should be treated as a single dose container/vial with the remains being discarded within 6 hours of compounding.

20. What concepts, at a minimum, should be taken into consideration when determining drug stability?

Pharmacists should use professional judgment to determine appropriate references of chemical stability information. When relying on information in studies, pharmacists should have at least two articles which justify the assigned stability. If stability is determined by extrapolating information from a reference source, then the pharmacist must ensure that the drug stability in the reference source is not concentration dependent. The process used by the pharmacist to determine drug stability should be well-documented and maintained for inspector review.

21. What are some important considerations regarding membrane filtration and filter integrity testing, aka bubble point testing?

Membrane filtration may be accomplished using a 0.22 micron filter. It is important to note that sterility testing cannot be accomplished by simply performing membrane filtration. Filter integrity testing, also known as a bubble point test, must be performed to verify that the filter was successful in its application. Smaller disc filters may have filter volume limitations which must be taken into consideration. Because it is known that filtration has not always been successful in preventing the passing through of microorganisms, pharmacists must always build quality processes into their sterile compounding to minimize the risk and the introduction of contamination.

22. What are some best practices for performing required media fill testing and gloved fingertip sampling?

Persons performing high-risk level CSPs must successfully pass media-fill testing prior to initially compounding sterile products and semi-annually (within 6 months of the last testing). Persons performing low or medium-risk level CSPs must successfully pass media-fill testing prior to initially compounding sterile products and annually (within 12 months of the last testing). Persons who fail a media-fill test may not perform sterile compounding prior to retraining and receipt of a passing media-fill test.

Media fill testing should mimic the most challenging sterile compounding activity performed by those persons. Robust documentation regarding the media-fill testing process and individual testing must be maintained which documents, at a minimum, the media growth to include lot

and expiration date, number of days in incubator, incubator temperature, name of person being tested, dates testing performed, results of growth. Blanks in the form used to document media fill testing should be evaluated and corrected to ensure an accurate testing process.

Glove finger tip testing verifies the person can properly don gloves without contaminating them and is routinely disinfecting them. To improve compliance with required testing, pharmacists should consider performing media-fill testing and glove finger tip testing around the same time that environments are being certified. Employees who use isolators must also perform gloved fingertip sampling by donning sterile gloves within the ISO Class 5 main chamber and testing those gloves.

23. How often must air and surface sampling be performed?

USP requires air and surface sampling to be performed "periodically". The Board advises that air and surface sampling should be performed at least annually. Air sampling shall be conducted using volumetric air sampling equipment and the appropriate media (bacterial sampling for all risk levels and fungi sampling for high-risk level compounding operations). It may be performed by pharmacy personnel or outsourced.

24. What minimally should be taken into consideration when having primary and secondary engineering controls certified?

Certification and testing of primary (LAFWs, BSCs, CAIs and CACIs) and secondary engineering controls (buffer and ante areas) shall be 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. Pharmacists shall request written documentation from the certifying company explaining how the company's certifying processes fully comply with these standards. This shall include written acknowledgement that certification testing will be performed under dynamic conditions. Certifications issued shall specifically indicate the ISO standard for each primary and secondary engineering control and not simply indicate "passed".

25. What minimally should be taken into consideration when compounding multidose vials?

Multidose vials of CSPs must comply with USP Chapter <51>. It must be determined that the preservative being used is bacteriostatic, fungistatic, effective at maintaining sterility for 28 days, and does not interact with the drug. Antimicrobial preservatives cannot be used as a substitute for good compounding practices.

26. What BUDs are recommended for non-sterile compounded products?

USP Chapter <795> makes the following recommendations for assigned BUDs of non-sterile compounded products:

Nonaqueous formulations - The BUD is not later than the time remaining until the earliest expiration date of any API or 6 months, whichever is earlier.
Water-Containing Oral Formulations - The BUD is not later than 14 days when stored at controlled cold temperatures.

Water-Containing Topical/Dermal and Mucosal Liquid and Semisolid Formulations – The BUD is not later than 30 days.

These maximum BUDs are recommended for nonsterile compounded drug preparations in the absence of stability information that is applicable to a specific drug or preparation. The BUD shall not be later than the expiration date on the container of any component.

27. May a non-sterile compounded product be assigned an extended BUD beyond the recommendations in USP Chapter <795>?

The Board advises that non-sterile compounded products should not be assigned an extended BUD unless the pharmacist maintains full documentation to justify the appropriateness of the extended BUD.

28. Under what conditions may a glove box be used to perform sterile compounding?

The glove box, referred to as an isolator (CAI/CACI) in Chapter <797>, must be placed in an ISO 7 buffer area UNLESS it meets all of the following conditions listed in USP Chapter 797:

- The isolator shall provide isolation from the room and maintain ISO Class 5 during dynamic operating conditions, including transferring ingredients, components, and devices into and out of the isolator and during preparation of CSPs.
- Particle counts sampled approximately 6 to 12 inches upstream of the critical exposure site shall 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.[8]

It is incumbent upon the compounding personnel to obtain documentation from the manufacturer that the CAI/CACI will meet this standard when located in environments where the background particle counts exceed ISO Class 8 for 0.5-μm and larger particles. When isolators are used for sterile compounding, the recovery time to achieve ISO Class 5 air quality shall be documented and internal procedures developed to ensure that adequate recovery time is allowed after material transfer before and during compounding operations.

If the primary engineering control (PEC) is a CAI or CACI that does not meet the requirements above or is a LAFW or BSC that cannot be located within an ISO Class 7 buffer area, then only low-risk level nonhazardous and radiopharmaceutical CSPs pursuant to a physician order for a specific patient may be prepared, and administration of the CSP shall commence within 12 hours of preparation or as recommended in the manufacturer's package insert, whichever is less.

The weighing of chemicals must occur in at least ISO Class 8 conditions. An isolator used to compound hazardous drugs (with exception of "low volume") must be located in a separate negative pressure room and exhausted outside.

29. May hazardous sterile products be compounded in the same hood as non-hazardous sterile drugs?

No. Hazardous sterile products may not be compounded in the same hood as non-hazardous CSPs.

30. Under what conditions may hazardous drugs be compounded in a cleanroom with positive air pressure?

USP allows a "low volume" of hazardous CSPs to be compounded in a cleanroom with positive air pressure, however, USP does not currently define the term "low volume". The "low volume" hazardous CSPs must be compounded under two tiers of containment, the isolator or biologic safety cabinet and closed system transfer device.

31. Must a compounding pharmacy using Schedule II powders comply with the perpetual inventory requirements of Regulation 18VAC110-20-240?

Yes.

32. Must bladder irrigation fluids and irrigations for wounds be prepared in a sterile manner in compliance with USP-NF requirements?

Yes. USP Chapter <797> states that for the purposes of the chapter, a compounded sterile product includes any of the following: compounded biologics, diagnostics, drugs, nutrients, and radiopharmaceuticals, including but not limited to the following dosage forms that must be sterile when they are administered to patients: aqueous bronchial and nasal inhalations, baths and soaks for live organs and tissues, injections (e.g., colloidal dispersions, emulsions, solutions, suspensions), irrigations for wounds and body cavities, ophthalmic drops and ointments, and tissue implants.

33. May a pharmacist provide a compounded drug to another pharmacy or veterinarian who will then dispense the drug to his client?

No. Va Code §54.1-3410.2 indicates pharmacists shall not distribute compounded drug products for subsequent distribution or sale to other persons or to commercial entities, including distribution to pharmacies or other entities under common ownership or control with the facility in which such compounding takes place.

VA Code §54.1-3410.2 does authorize pharmacists to provide compounded drug to practitioners of medicine, osteopathy, podiatry, dentistry, or veterinary medicine to administer to their patients in the course of their professional practice, either personally or under their direct and immediate supervision. The compounded drug must be labeled with (i) the statement "For Administering in Prescriber Practice Location Only"; (ii) the name and strength of the compounded medication or list of the active ingredients and strengths; (iii) the facility's control number; (iv) an appropriate beyond-use date as determined by the pharmacist in compliance with USP-NF standards for pharmacy compounding; and (v) quantity.

34. May a prescriber or patient obtain a compounded sterile product from an out-of-state pharmacy that is not registered by the Virginia Board of Pharmacy as a nonresident pharmacy?

No, only nonresident pharmacies registered by the Virginia Board of Pharmacy may ship compounded sterile products into Virginia. Verification of registration may be determined at https://secure01.virginiainteractive.org/dhp/cgi-bin/search_publicdb.cgi by searching the business name and choosing the occupation of "non-resident pharmacy".

NHIA
National Home Infusion Association
Providing solutions for the infusion therapy community

January 30, 2014

Caroline D. Juran
Executive Director
Virginia Board of Pharmacy
Perimeter Center
9960 Mayland Drive, Suite 300
Henrico, Virginia 23233-1463

Re: Requirement for Non-resident Pharmacies to Submit Current Inspection Report (Guidance Document 110-38)

Dear Ms. Juran:

The National Home Infusion Association (NHIA) is writing to comment on the Requirement for Non-resident Pharmacies to Submit Current Inspection Report Guidance (Guidance Document 110-38) that was revised on June 18, 2013. NHIA is a national membership association for clinicians, managers and organizations providing infusion therapy services for patients in the home and outpatient settings.

Many NHIA members provide infusion therapy to patients in Virginia, and several of those members are non-resident pharmacies. NHIA understands the need to ensure safety for pharmacies that compound product and dispense those products in Virginia, and we commend the Board for adopting the standards delineated by the United States Pharmacopeia (USP). The NHIA has long been a proponent of the standards for compounded product contained in USP <797>.

NHIA readily agrees that non-resident pharmacies should be USP <797> compliant. Many non-resident NHIA members are accredited by organizations that require adherence to USP 797 standards, but we understand that under your Guidance Document 110-38 these organizations must obtain their current inspection reports from a licensing or regulatory agency of jurisdiction or from the National Association of Boards of Pharmacy (NABP). In states where USP is not the regulatory standard, the only option for a pharmacy is to receive the current inspection report from the NABP. This appears to be a costly and unnecessary step. Instead, NHIA recommends that the Commonwealth of Virginia explore other means of producing an inspection report, such as requiring confirmation from accrediting bodies that inspect to USP <797> standards. This would simplify the process for both Virginia and the pharmacy that has already been accredited for USP <797> compliance.

100 Daingerfield Road • Alexandria, VA 22314 • *Phone:* 703.549.3740 • *Fax:* 703.683.1484 • www.nhia.org

Please feel free to have your staff contact Kendall Van Pool, NHIA Vice President of Legislative Affairs, at (703) 838-2664 or kendallvanpool@nhia.org should you want to discuss our comments further. Thank you for your consideration of NHIA's comments.

Sincerely,

Russell Bodoff
President & CEO
National Home Infusion Association

CC: Jody H. Allen, Board Chair
Ellen B. Shinaberry, Board Vice-Chair

LDT Health Solutions, Inc.
38 Cedar Place
Wayne, NJ 07470
862.221.9575
www.LDTRx.com

6 February 2014

Virginia Board of Pharmacy
9960 Mayland Drive, Suite 300
Henrico, VA 23233-1463
804.367.4456
Ms. Caroline D. Juran, Executive Director
pharmbd@dhp.virginia.gov

Dear Ms. Juran,

LDT Health Solutions is a medication safety and quality management consultancy founded by pharmacists and we are now in our eight year providing guidance, technical expertise, and regulatory support to clients nationwide. We specialize in the area compounding of sterile drugs.

Our practice has had the unique opportunity to lend its talents to several Boards of Pharmacy in varying capacities as well as to lecture, precept students, and have been involved in the development of plans-of-correction for many pharmacies resulting from the FDA recent stepped up auditing of compounding pharmacies in the wake of the terrible tragedy surrounding the New England Compounding Center (NECC). It is tragic that your commonwealth has had to bear the burden of 54 diagnosed cases of meningitis and 5 deaths.

Since 2011 LDT has offered as part of it services auditing and compliance support for all models of compounding facility. These reports have been part of FDA actions, State Board of Pharmacy proceeding or third party payor audits to assure compliance to all prevailing statues rules and regulations surrounding the compounding of sterile preparations by Pharmacies.

We have been approached by several pharmacies both inside and outside of the Commonwealth to audit their compounding operations and provide standard reporting to be used either as proof of compliance to prevailing VA statute or to support their petition to the VA Board as part of their application as a Non-Resident Pharmacy. We have conducted these same activities in the states of NJ, NY, SC, and PA to date, and have had the State Boards in those jurisdictions accept our detailed Gap Analysis Tool as independent proof of compliance.

For the Board's information I have included a sample of the questions library and a sample report for you review. The materials attached represent our years of professional experience and expertise and are the intellectual property of LDT protected by copyright. We share them in confidence with the Board so that you may review them and possibly provide a determination whether the VA Board

LDT Health Solutions, Inc.
38 Cedar Place
Wayne, NJ 07470
862.221.9575
www.LDTRx.com

would be inclined to accept our independent assessment of a Pharmacy's sterile compounding compliance for either resident or non-resident pharmacies. Under VA 54.1-3434.1 A 3 of your drug control Act.

We are aware that currently VA only recognizes the NABP process, but it is our hope that we may convince the Board that our process is an independent and qualified as theirs since this is our primary practice area. With the nationwide effort to respond to the DQSA and to harmonize all State regulations with that Federal Act there has been a shortage of reliable resources in this area. It is not our intent to make this our primary business offering; however, where appropriate we feel that we can serve the public health by assisting pharmacies and Boards alike in the assurance of competent, qualified pharmacy providers so that critical access to this care is available for all.

To support our query I have included the CVs of both my partner and myself along with a reference list of fellow Board Executives who are familiar with our documents and methods.

I know this request is somewhat unusual but these are unfamiliar times within Pharmacy practice and out intent is only to offer what we feel are appropriate solutions.

Respectfully submitted,

Louis S. Diorio, R.Ph., FAPhA
Principal

Please contact us today for further information. Visit us on the web: www.LDTRx.com.

CC: File
Attachments

LDT Health Solutions, Inc.
38 Cedar Place
Wayne, NJ 07470
862.221.9575
www.LDTRx.com

July 6, 2011

Screening Questions for LDT's Proprietary <797> GAP Tool

General Information:

The following questions will be used to determine the precise USP <797> questions that will be applicable to your specific facility.

Familiarity with the definitions in USP <797> will be helpful in the completion of these questions.

Not all questions will need to be answered.

Upon completion of these questions you will need to fax the answers to Dave Thomas fax (847) 854-1760. A survey specific to your facility will be prepared and e-mailed to you for completion.

If you have questions or comments my contact information is:

David L. Thomas, R.Ph.,M.B.A.
Principal
LDT Health Solutions, Inc.
1025 Gaslight Drive
Algonquin, IL 60102-3213
Cell (847) 846-3753
Fax (847) 854-1760
Office (847) 458-8434
mailto:DThomas@LDTRx.com
Web Site www.LDTRx.com

LDT health solutions
Pharmacy Consultants

LDT Health Solutions, Inc.
38 Cedar Place
Wayne, NJ 07470
862.221.9575
www.LDTRx.com

Facility Information	
Facility Name:	
Address 1:	
Address 2:	
City:	
State:	
Zip Code:	
Phone:	
Fax:	
Contact Information	
First Name:	
Last Name:	
Suffix:	
Title:	
Phone:	
Email:	
Compounding Area Information	
Name:	
Location:	

Beyond Use-Dating Classification		
1. Are Compounded Sterile Preparations (CSPs) being compounded in a Primary Environmental Control (PEC) ["hood"]?	○ Yes Go to Question 2	○ No Go to Question 11
2. Is the Primary Engineering Control (PEC) ["hood"] certified to ISO Class 5?	○ Yes Go to Question 3	○ No Go to Question 11
3. Is the Secondary Environmental Control (SEC) ["room"] certified to ISO Class 7?	○ Yes Go to Question 4	○ No Go to Question 6
4. Do personnel follow Personnel Cleansing and Garbing and Additional Personnel requirements prior to compounding?	○ Yes Go to Question 5	○ No Go to Question 11
5. Are the specifications in 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 Air Sampling (ES) Testing being followed as described in USP <797>?	○ Yes Go to Question 11	○ No Go to Question 11
6. Is a Compounding Aseptic Containment Isolator (CACI) ["glove-box"] in use?	○ Yes Go to Question 7	○ No Go to Question 8
7. Does the CACI require a SEC?	○ Yes Go to Question 8	○ No Go to Question 11

LDT Health Solutions, Inc.
38 Cedar Place
Wayne, NJ 07470
862.221.9575
www.LDTRx.com

8. Is the CACI located in area with unsealed windows or doors that connect to the outdoors or high traffic flow or adjacent to construction sites, warehouses or food preparation?	○ Yes Go to Question 11	○ No Go to Question 9
9. Do personnel follow Personnel Cleansing and Garbing and Additional Personnel requirements prior to compounding?	○ Yes Go to Question 10	○ No Go to Question 11
10. Are the specifications in 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 Air Sampling (ES) Testing being followed as described in USP <797>?	○ Yes Go to Question 11	○ No Go to Question 11
High Risk Preparation Classification		
11. Are any CSPs prepared from non-sterile products (liquid or powders)?	○ Yes Go to Question 12	○ No Go to Question 19
Filtration Sterilization Classification		
12. Is filtration being utilized to sterilize High-Risk CSPs?	○ Yes Go to Question 13	○ No Go to Question 13
Steam Sterilization Classification		
13. Is steam being utilized to sterilize High-Risk CSPs?	○ Yes Go to Question 14	○ No Go to Question 14
Dry Heat Sterilization Classification		
14. Is dry heat being utilized to sterilize High-Risk CSPs?	○ Yes Go to Question 15	○ No Go to Question 15
Depyrogenation Classification		
15. Is dry heat being utilized to for depyrogenation of glassware and glass vials?	○ Yes Go to Question 16	○ No Go to Question 16
High Risk Testing Classification		
16. Are controlled room temperature High-Risk CSPs dispensed after 24 hours?	○ Yes Go to Question 19	○ No Go to Question 17
17. Are refrigerated High-Risk CSPs dispensed after 3 days at a cold temperature?	○ Yes Go to Question 19	○ No Go to Question 18
18. Are High-Risk CSPs prepared in batches greater than 25?	○ Yes Go to Question 19	○ No Go to Question 19
Medium Risk Preparation Classification		
19. Are multiple individual or small doses of sterile products combined or pooled to prepare a CSP that will be administered either to multiple patients or to one patient on multiple occasions?	○ Yes Go to Question 25	○ No Go to Question 20
20. Does the compounding process include complex aseptic manipulations other than a single-volume transfer?	○ Yes Go to Question 25	○ No Go to Question 21
21. Does the compounding process require unusually long duration, such as that required to complete dissolution or homogeneous mixing?	○ Yes Go to Question 25	○ No Go to Question 22
22. Are CSPs compounded with aseptic manipulations entirely within ISO Class 5 or better air quality using only sterile ingredients, products, components, and devices?	○ Yes Go to Question 23	○ No Go to Question 25

LDT Health Solutions, Inc.
38 Cedar Place
Wayne, NJ 07470
862.221.9575
www.LDTRx.com

23. Does compounding involve 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, vial) of sterile product or administration container/device to prepare the CSP?	○ Yes Go to Question 24	○ No Go to Question 25
24. Are manipulations 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?	○ Yes Go to Question 25	○ No Go to Question 25
Medium Risk Testing Classification		
25. Are controlled room temperature Medium-Risk CSPs dispensed after 30 hours?	○ Yes Go to Question 28	○ No Go to Question 26
26. Are refrigerated Medium-Risk CSPs dispensed after 9 days at a cold temperature?	○ Yes Go to Question 28	○ No Go to Question 27
27. Are frozen Medium-Risk CSPs dispensed after 45 days in solid frozen state between −25° and −10°C?	○ Yes Go to Question 28	○ No Go to Question 28
Low Risk Preparation Classification		
28. Are there any CSPs compounded involving 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, vial) of sterile product or administration container/device to prepare the CSP?	○ Yes Go to Question 29	○ No Go to Question 32
Low Risk Testing Classification		
29. Are controlled room temperature Low-Risk CSPs dispensed after 48 hours?	○ Yes Go to Question 32	○ No Go to Question 30
30. Are refrigerated Low-Risk CSPs dispensed after 14 days at a cold temperature?	○ Yes Go to Question 32	○ No Go to Question 31
31. Are frozen Low-Risk CSPs dispensed after 45 days in solid frozen state between −25° and −10°C?	○ Yes Go to Question 32	○ No Go to Question 32
General Classification (Answer All)		
32. Are hazardous drug CSPs being prepared? (i.e. Chemo)	○ Yes	○ No
33. Are Radiopharmaceuticals CSPs being prepared?	○ Yes	○ No
34. Are allergen extracts CSPs being prepared?	○ Yes	○ No
35. Is cleaning equipment reused when sanitizing the compounding area?	○ Yes	○ No
36. Are Automated Compounding Devices besides those used for Parenteral Nutrition in use?	○ Yes	○ No
37. Are parenteral nutrition CSPs being prepared with automated compounding devices (ACDs)?	○ Yes	○ No
38. Are any returned CSPs re-dispensed?	○ Yes	○ No
39. Are CSPs being distributed to locations packing or transporting CSPs being shipped to other facilities?	○ Yes	○ No
40. Is patient or caregiver training being routinely preformed?	○ Yes	○ No

LDT Health Solutions, Inc.
38 Cedar Place
Wayne, NJ 07470
862.221.9575
www.LDTRx.com

Please Fax Response to Dave Thomas (847) 854-1760

LDT
health solutions
Pharmacy Consultants

LDT health solutions
Pharmacy Consultants

USP <797> Electronic GAP Tool

LDT Health Solutions, Inc.
38 Cedar Place
Wayne, NJ 07470
862.221.9575
www.LDTRx.com.com

LDT Health Solutions Inc. (LDT) is a total quality management firm, specializing in Controlled process and quality management strategies for the pharmacy community.

LDT has over three decades of experience in extemporaneous Pharmacy compounding, cGMP manufacturing, Homecare product preparation, and Hospital clean room applications. LDT is a leader in regulatory affairs and compliance, and can offer its expertise to assist your organization in bringing forth the highest quality preparations and services possible.

We have technical expertise in automated compounding devices, software, and custom compounding methodologies. Through our use of "point of failure" analysis we can develop unique solutions for your practice setting and particular application, enlisting a blend of technical, automation, software and controlled process thinking.

Please visit us today at www.LDTrx.com to see how LDT can partner with you to make your practice all it can be.

LDT
health solutions
Pharmacy Consultants

LDT's mission is to provide value through experience, expertise, and unsurpassed customer service.

LDT's Electronic Gap tool- LDT's <797> Web-based Gap tool will assist your customer's compounding operation conduct a situational analysis to establish a baseline for their compliance, in order to create an action plan for the pharmacy to meet the standards set forth in USP. The tool is easy to use and will help them evaluate their current sterile compounding operations against the <797> standards.

The tool mirrors the quality domains set forth in the actual USP Chapter. In fact, based upon the responses given by the customer, the tool automatically gives the exact citation within USP General Chapter <797> (for both positive and negative responses). This reduces the possibility of ambiguity and erroneous interpretation of some of the chapter's provisions.

The tool will help the customer to generate a high level situational analysis of their compounding operations as compared with all the quality domains in USP General Chapter <797> which will then allow you to address shortcomings in their operations.

The tool comes complete with a 45 minute (approximately) live consultation with a Pharmacist to discuss the findings and assist with the formulation of the customer's action plan to reach compliance.

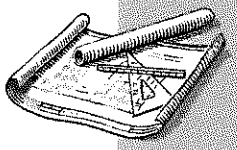
PLEASE NOTE: The consultation is scheduled by mutual agreement, but only after the customer has completed the entire gap tool assessment.

Work flow & Design Services

LDT has expertise in workflow and design planning for all type of pharmacy and compounding operations.

These applications include:

- Hospitals
- Home Care Providers
- Out patient clinics and Ambulatory Infusion Centers
- Pharmacies
- Physician Office Practices
- Radio Pharmacies & Nuclear Medicine departments
- Regional Compounding Centers



Please visit us at
www.LDTRx.com
to learn more about our innovative services

For further information contact:

Lou Diorio, RPh
Principal
201.738.9125
LSDiorio@LDTRx.com

Dave Thomas, RPh, MBA
Principal
847.846.3753
DThomas@LDTRx.com

Offices:
38 Cedar Place
Wayne, NJ 07470

Phone/fax: 862.221.9575
www.LDTRx.com

LDT health solutions
Pharmacy Consultants

Quality Management Solutions for all your Healthcare applications.

LDT Health Solutions, Inc.

LDT Health Solutions, Inc.

862.221.9575

24

Consulting Services

LDT Health Solutions is a Health care consulting firm founded by pharmacists to provide the highest quality consulting services nationwide.

LDT provides its expertise to all areas of Pharmacy practice including:

- Regional Compounding
- Outsourcing / Insourcing of compounding services
- USP <795> & <797> compliance
- Radio Pharmaceutricals & Nuclear Medicine
- Regulatory Affairs
- Quality Management

LDT mission is to provide value through experience, expertise, and unsurpassed customer service.

LDT health solutions
Pharmacy Consultants

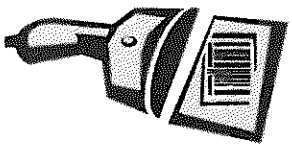
Our Services Include:

- Automated Compounding Device Solutions
- Bar coding Technologies
- Competency based training development
- Continuing Education Presentations and Clinical Presentations
- Sterile Compounding Expertise
- Compounding Methodologies & Formulations
- Staff Education and Development
- Controlled Process & Policy Development
- Health care Executive Coaching & Mentoring
- Clean Room Design & Construction
- Formulary Management Consulting
- Medical Information Systems
- On-line survey tools—development & analysis
- Outsourcing / Insourcing of Compounding
- Quality Management Planning
- Regulatory Affairs and Compliance
- Sales & Marketing Strategies

Health Technology

LDT Health Solutions is a leader in technology solutions for all your sterile compounding needs. We specialize in:

- TPN Usage analysis
- Regionalization Solutions
- Centralization Solutions
- System Integrations
- Bar Coding
- Custom label designs



We are experienced in all bar code formats and integration with smart pump technology

LDT Health Solutions, Inc.

38 Cedar Place
Wayne, NJ 07470

Phone/fax: 862.221.9575
www.LDTRx.com

LOUIS S. DIORIO, R.Ph., FAPhA
38 Cedar Place
Wayne, New Jersey 07470
(201) 738-9125
Lsdiorio@LDTRx.com

HEALTH SYSTEM CONSULTANT

Pharmacy and Healthcare Author & Educator

Highly qualified executive offering more than 25 years of multi-faceted healthcare management experience. Results-focused with proven ability to develop new marketing strategies and fresh clinical approaches to the delivery of health services with the highest quality and the greatest possible efficiency. Superior record of delivering simultaneous large-scale, mission critical projects. Team based management style and excellent interpersonal, communication, and presentation skills.

Innovative pharmacy educator offering fresh insight and a passion for balancing proven science with new technologies. Author and Contributor to professional, technical and trade publications. Dynamic leader and mentor, able to build team cohesion and inspire individuals to ever-higher levels of achievement.

- Automated Compounding Technologies
- Bar Coding Technologies
- Bid and contract negotiations
- Business process review
- Clinical Presentations & Public Speaking
- Compounding Methodologies and Formulations
- Compounding Expertise & Compliance (USP <795> and <797>)
- Continuing Education & Staff Development
- Controlled Process & Policy Development
- Executive Coaching & Mentoring
- Facility Design & Construction
- Formulary management
- Large scale project management
- Long term care consulting
- Management consulting
- Market surveys and data collection
- Medical Information Systems
- Medication Safety
- Outsourcing - Contract Compounding
- Productivity enhancement
- Quality Management Planning
- Regulatory Affairs & Compliance
- Sales & Marketing Strategies
- Strategic planning and execution
- White Paper development & Medical Writing

26

PROFESSIONAL EXPERIENCE

LDT Health Solutions, Inc.
Formerly - Certified Consultant Pharmacists Healthcare Associates, Inc.
Wayne, NJ
Principal (2006 – Present)

LDT Health Solutions, Inc. is a NJ based Medication Safety & Quality Management Healthcare consulting firm founded to provide its expertise to several areas of pharmacy practice including Regional Compounding (both In-sourcing & Out-sourcing), <USP 797> compliance, Regulatory Affairs, and Quality Management. LDT's mission is to provide value through experience, expertise, and unsurpassed customer service.

www.LDTRx.com

SOLUNET, LLC
(A WHOLLY OWNED SUBSIDIARY OF CORAM INC.)- Totowa, NJ

Vice-President of Operations (2004 - 2006)
Service Center Manager – Totowa, NJ (2003 – 2004)

Leader of the corporate Operations Group. Primary responsibilities included: Facility design and construction, sales and customer development, as well as direction of daily production operations. SoluNet was a leader in the provision of compounded sterile preparations to Hospitals and Long-term Care vendors. The company's major product lines were TPN, Cardioplegia, CVVH & CRRT, as well as custom large & small volume parenterals. SoluNet lead the Nation in USP 797 compliant clean room facilities, using unique technologies and software to provide the highest quality preparations.

HEBREW HOSPITAL CORPORATE SERVICES
(HHCS, INC.) – Bronx, NY

Chief Clinical Operations Officer (1998 - 2003)
Director of Central Supply Services (1995 – 1998)
Director of Pharmacy Services (1994 – 1998)

Recruited initially to modernize, expand and market pharmacy services for the 480 Bed SNF main campus. Challenged in 1995 with the re-engineering of purchasing services, materials management, and the bids & contracts process. Reorganized and consolidated all clinical, diagnostic & imaging, and outpatient services in 1998, adding sub-acute, hospice, and respite beds to the health-system. Expanded operations to multiple campuses in 1998, and transformed this organizational unit into a multi-disciplinary clinical leader. Implemented multiple software applications over the WAN of the health system.

27

As the head of the Operations Team, I was responsible for all Clinical Service components within this multi-centered 100 million-dollar health system it was my paramount responsibility to balance the clinical concerns of the system with the logistical realities of the current market. Other duties included Managed Care Contracting, HIPAA Compliance, P&T Responsibility and Strategic planning and marketing. The system contained over 700 nursing home beds (including sub-acute, respite & hospice beds), two adult day care Programs, a long term home healthcare agency, a licensed home care services agency, and a senior housing division.

CAREMARK, INC.
(A BAXTER HEALTHCARE COMPANY) – Totowa, NJ

Manager of Pharmacy Services (1993 – 1994)

Complete responsibility for the Pharmacy, Technical, Support, and Customer Service personnel in one of the company's premier JCAHO accredited branches. Paramount duties in this area were staff development, clinical and technical assistance, along with the total quality management of the clinical operations. Responsible for implementation of the Branch Quality Management Plan. Integral in the management of the local patient outcomes database. Prescription compounding production at this facility increased to 15,000 parenteral dosage units monthly, and staff was expanded to maintain a patient base of over eight hundred. Special projects included, development of a home blood transfusion service program, specialized clinical support for off-site oncology business initiatives and analysis and implementation of clinical regionalization projects.

OCEAN BREEZE PHARMACY & INFUSION CARE
(A DIVISION OF STATEN ISLAND UNIVERSITY HOSPITAL) – Staten Island, NY

General Manager of Pharmacy Services (1990 – 1992)
Dispensing Supervisor / Infusion Pharmacist (1989 – 1990)

Hired initially to supervise the compounding area and oversee the production of extemporaneously compounded products. In charge of policy development for patient counseling and consultation, including institutional and home visits. Coordinated outside nursing to provide full service homecare.

As the General Manager, I was charged with the overall supervision of pharmacy, technical, and clerical personnel. Administrative duties included third party contract billing and negotiations. Responsible for overseeing billing and record keeping functions as well as accounting procedures. Direct design & development of both prescription and over-the-counter market programs. Developed special software applications to monitor specific demographics and track drug usage as well as physician prescribing habits. Expansion of patient base enabled this multicenter business group to exceed sales projections for

three straight years. In 1992 the total annual sales were in excess of ten million dollars.

SAV-ON / SUPER-X DRUG, INC. – Staten Island, NY

Assistant Manager / Pharmacist (1988-1989)
Responsibilities included supervision, training, and scheduling of technical staff. Aided in increasing prescription volume by development of special community outreach programs. Encouraged patient dialogue through counseling to increase ancillary sales.

THE UPJOHN COMPANY
(NEW YORK SALES AREA) – Kalamazoo, MI

Sales Representative (Level II) / Field Trainer (1985-1988)
Influenced physician-prescribing habits daily. Served a large inner city territory encompassing both primary care and hospital based prescribers. The average sales growth across my tenure was over twenty percent, and in the final year the total combined sales for the territory was over $1.2 million dollars. Additional duties included assisting the district manager in interviewing, screening, and training of new sales personnel.

EDUCATION

Arnold and Marie Schwartz College of Pharmacy, Long Island University
(Bachelor of Science in Pharmacy, June 1985)
Degree awarded with the following:
Member of the Executive Dean's Society
Member of the University's Honors Program

HONORS AND AWARDS

- 2014 Fellow of American Pharmacists Association
- 2013-2014 Chair of the APhA's Compounding Special Interest Group (SIG)
- 2008-2009 Chair of APhA Academy of Practice and Management, Administrative Practice Section
- Assistant Professor of Pharmacy Practice, Schwartz College of Pharmacy, LIU (1999-Present)
- Member of the Experiential Education Council, Schwartz College of Pharmacy, LIU (2002-2010)
- Member of the Alumni Board of Directors, Schwartz College of Pharmacy, LIU (1990-2000) (2011-Present)
- Regent of the NY Graduate Chapter, Kappa Psi Pharmaceutical Fraternity (1990-Present)
- National Public Relations Director, Kappa Psi Pharmaceutical Fraternity (1995-1999)
- Delegate to American Pharmaceutical Association's House (1992-1995,1998, 2007-2009)
- Executive Board Member, Empire State Pharmaceutical Society (1991-1993)
- National Patient Counseling Competition Finalist (Sponsored by the USP, 1985)

CONSULTING EXPERIENCE AND APPOINTMENTS

- ***New York State Board of Pharmacy (IV Rules Sub-Committee)***
  Since 2011, has assisted the Board in developing the rules, regulations and guidance for sterile preparations compounding. Acting in a supportive capacity has advised the Executive Director and the Board on a wide variety of compounding issues and regulatory matters.

- ***New Jersey State Board of Pharmacy (Rules and Regulations Committee)***
  Since 1993, has assisted the Board in developing major portions of the Compounded Sterile Preparations regulation for Department of Consumer Affairs. Working with the NJ Attorney General's Office in a consultant capacity, assisted in developing a working enforcement guideline for the IV regulations. In 2006, as member of the State Board's select committee on <USP 797>, helped develop policy, regulation, and statutory recommendations to the Board. Since 2013 LDT is among a select few Board approved independent monitors to assure that NJ pharmacies with difficulties keep pace with the evolving practice area of Sterile IV Compounding in the State.

PROFESSIONAL LICENSURE

- New York
- New Jersey

PROFESSIONAL SOCIETY MEMBERSHIP

- American Pharmacists Association
- American Society of Health System Pharmacists
- Kappa Psi Pharmaceutical Fraternity

PERSONAL DATA

- Eagle Scout with Silver Palm (Boy Scouts of America)

REFERENCES

Furnished upon request.

1025 Gaslight Terrace
Algonquin, IL 60102-3213
Phone (847) 658-1915

David L. Thomas, R.Ph., M.B.A.

Work experience

8/06 – Present *LDT Health Solutions, Inc.*

Principal

- LDT Health Solutions, Inc provides its expertise to all areas of pharmacy practice including regional compounding management, <USP 797> compliance, regulatory affairs, and Quality management. LDT's mission is to provide value through experience, expertise and unsurpassed customer service.

6/03 – 8/06 *SoluNet LLC*

Director of Field Operations

- SoluNet Facility builds and technology designs. Setup of all customers for SoluNet Product offerings. Daily support of all operational aspects for all facilities. Responsible for development of new software for SoluNet Operations. These products included SoluNet Client, Server, Label Monitor and Compounding Monitor. I developed the program to analysis customer using Baxter's TPN software and the program to allow the TPN-PC Plus program to print to Zebra printers.

11/98 – 6/03 *Baxter Clintec Nutrition Division*

Technology Development and Implementation Manager

- Support development of new software and hardware technologies. Responsible for participation in testing of new software and hardware. Support new and existing customers. Identify new technology applications/opportunities

9/94 – 11/98 *Baxter COMPASS*

Systems Manager

- Designed and supported all aspects of COMPASS Systems Operations. Developed and implemented COMPASS facility networks with redundancy (no service failure 7/93 to present). Supported 7 LANs with interconnections and internet access. Developed, implemented and supported Regionalization/Centralization program. Maintained 100% service and product levels.

8/92 – 9/94 *Baxter Clintec Nutrition Division*

Product Manager

- Responsibility with design, development, testing, implementation, and rollout of the Multitask Operating System Version 2.3. Developed, tested, and implemented the Compounding Interface Manager. Developed Operator's Manual for Version 2.3. Helped validate and test Multitask Operating System Version 2.2. Developed initial TPN system for COMPASS. Maintained billing and support functions for COMPASS facilities. Oncall for COMPASS sites.

6/90 – 8/92 *Baxter Clintec Nutrition Division*

Technical Service Specialist

- Trained and implemented Multitask Operating System at customer sites. Rotated through 24hour on call service. Designed, developed and implemented Technical Service Phone Log System. Setup initial tests for Off-Site Multitask Operating System compounding.

6/89 – 6/90 *Baxter Dialysis Division*

Dialysis Pharmacy Manager

- Full responsibility for all aspects of Renal Dialysis Pharmacy including: Direct interface with physicians and nurses for peritoneal solutions. Supervise and direct scheduling of dialysis formulations. Human resources and staffing issues. Develop and execution of operational budgets. Directly accountable for adherence to all S.O.P.'s, training and compliance. Monitoring purchasing and physical inventories. Maintain database information for all patient prescriptions. Prepare monthly report of activity. Interface with Divisional in order entry, marketing, engineering, sales force, QARA, human resources, and operations.
-

6/88 – 6/89 *Baxter Chemotherapy Division*

Chemotherapy Pharmacy Manager

- Full responsibility for managing Baxter Chemotherapy Pharmacy and its eleven employees. Prepare monthly production reports detailing employee hours, meetings, complaints, and problems. Provide information to sister pharmacies on drug stability and Baxter products. Confer with groups within Baxter that make infusors. Mediating transfer of managerial responsibilities to Caremark of Cincinnati, Louisville, and Minneapolis.

6/88 – 6/89 *St. Joseph Medical Center*

Staff Pharmacist

- Duties include experience with traditional and computerized pharmacy operations: fill and check unit dose; prepare IV admixture solutions including chemotherapy and hyperalimentation fluids; provide supervision and direction to pharmacy technicians; provide information to professional medical staff regarding drug interactions, adverse drug reactions, interactions and contraindications. Redesigned the unit dose area to operations more efficient.

Publications/ Technical Papers

Ensure Outsourcing Quality Control during Shortages *in Pharmacy Purchasing & Products Dec 2011*

Lean Concepts & Pharmacy *Baxa Corporation Technical Paper 2011*

Avoid Common Problems in the Cleanroom with Staff Training *in Pharmacy Purchasing & Products July 2011*

Implementing a Successful Regional Compounding Plan: Issues and

Requirements *Baxa Corporation Technical Paper 2010*

Determination of Beyond-Use Dates for Compounded Sterile Preparations (CSPs) *Baxa Corporation Technical Paper 2010*

Establishing a Successful Regional Compounding Program *in Pharmacy Purchasing & Products Oct 2010*

Evaluating and Training Compounding Personnel *in Pharmacy Purchasing & Products Sept 2010*

Making a Case for Automated Compounding Devices *in Pharmacy Purchasing & Products April 2010*

Choosing an Automated Compounding Device *in Pharmacy Purchasing & Products Dec 2009*

Tips for Sterility Testing *in Pharmacy Purchasing & Products Nov 2009*

Training and Evaluating Compounding Personnel *in Pharmacy Purchasing & Products Oct 2009*

Assigning Beyond-Use Dates for Compounded Sterile Preparations: Evaluating Stability Data *in Pharmacy Purchasing & Products Sept 2009*

Maximizing Outsourcing Options for Compounded Preparations *in Pharmacy Purchasing & Products July 2009*

Establishing a Budget for Cleaning the Cleanroom *in Pharmacy Purchasing & Products Feb 2009*

Making the Case for Incubators in Pharmacy *in Pharmacy Purchasing & Products Oct 2008*

Premix vs. Custom TPN *Baxa Corporation Technical Paper*

Safety Practices for TPN Compounding *in Pharmacy Purchasing & Products April 2006*

Increasing Your Compounding Speed and Accuracy: Automated Compounding Devices and Related Software *in Pharmacy Purchasing & Products Sept 2005*

Education

9/88 – 12/94 *Lewis University* *Romeoville, IL*
Management Information Systems M.B.A.

8/83 - Present *State of Illinois Registration*
Illinois Pharmacy License

9/78 - 5/83 *St. Louis College of Pharmacy* *St. Louis, MO*
B.S. of Pharmacy Degree.

1987 - Present *State of Illinois Registration*

Completion of Continuing Education courses for Illinois licensure.

LDT Health Solutions
PHARMACY CONSULTANTS

References for LDT Health Solutions, Inc.
Board of Pharmacy Contacts List

New York State Board of Pharmacy

Lawrence H. Mokhiber
Executive Secretary
NY State Education Department
Office of the Professions
State Board of Pharmacy
89 Washington Avenue
Albany, New York 12234-1000
518.474.3817 ext. 130
pharmbd@mail.nysed.gov

Board Members (NYBOP)

Leigh Brisco-Dwyer, PharmD.,FASHP
Chief Compliance Officer
North Shore LIJ Health System
1979 Marcus Ave
Suite E124
Lake Success, NY 11042
516. 396.6248
Ldwyer1@nshs.edu

Frank Snowski, RPh, MS
Executive Director of Pharmacy Services
Montefiore Medical Center
111 East 210th Street
New York, NY 10467
718. 904.2369
fsosnows@montefiore.org

New Jersey State Board of Pharmacy

Mr. Anthony Rubinaccio, RPh
Executive Director
New Jersey State Board of Pharmacy
124 Halsey Street, 6 Floor
Newark, NJ 07102
973.504.6450
RubinaccioA@dca.lps.state.nj.us

South Carolina Board of Pharmacy

Ms. Lee Ann Bundrick
Chief Drug Inspector/Administrator
South Carolina Board of Pharmacy
SC Dept. of Labor, Licensing and Regulation
110 Centerview Dr.
Columbia, S.C. 29210
(803) 896-4700
leeann.bundrick@llr.sc.gov

Other References

William M. Ellis, MS, R.Ph.
Executive Director
Board of Pharmacy Specialties
2215 Constitution Ave NW
Washington, DC 20037-2985
202.223.7195
wme@mail.aphanet.org

Eric Kastango, RP, MBA, FASHP
CEO
Clinical IQ, LLC
8 Briarwood Road
Florham Park, NJ 07932-2552
(973) 765-9393
eric.kastango@clinicaliq.com

Utah Attorney General's Office

Mr. Karl Perry, Esq.
Asst. Att. General
Commercial Enforcement Division,
The Division of Occupational &
Professional Licensing of the
Department of Commerce the State of
Utah
160 East 300 South, 5th Floor
PO BOX 140872
Salt Lake City, UT 84114-0872
(801) 366-0310

Ms. Brittany Butsch
Senior Investigator
Commercial Enforcement Division,
The Division of Occupational &
Professional Licensing of the
Department of Commerce the State of
Utah
160 East 300 South, 5th Floor
PO BOX 140872
Salt Lake City, UT 84114-0872
(801) 530-6493

Mississippi Board of Pharmacy

Cheri Atwood
Compliance Agent
Mississippi Board of Pharmacy
204 Key Drive, Suite D
Madison, MS 39110
CAtwood@mbp.state.ms.us
(662) 582-0038

ACHC

FOR PROVIDERS.
BY PROVIDERS.

May 7, 2014

Caroline D. Juran, RPh
Executive Director
Virginia Board of Pharmacy
9960 Mayland Drive, Suite 300
Henrico, VA 23233

Dear Ms. Juran,

Thank you for permitting ACHC to present its sterile and non-sterile pharmacy certification programs to your Board as a viable alternative to state licensure surveys. It is apparent that the missions of both of our organizations are aligned to ensure patient safety through high-quality compounded medications in the marketplace. ACHC can offer its certification program to the Virginia Board of Pharmacy as a compliance solution to be used in lieu of the inspection report from a regulatory board or the out of state jurisdiction the pharmacy is located in.

Since the introduction of its pharmacy program in 1996, ACHC has grown to become a leading national accrediting organization with more than 600 pharmacies accredited in the U.S. In addition, ACHC launched a compounding certification program for both non-sterile (ref. USP<795>) and sterile (ref. USP<797>) pharmacy compounding services in 2014. ACHC's certification program assesses the compounding process as defined by a specific set of standards that concentrate on the quality and consistency of medications produced. The certification program also requires evidence of continuous compliance to be submitted on an annual basis in addition to a site survey every three years.

ACHC delivers a consultative survey approach through its network of knowledgeable Surveyors who offer guidance based on industry-specific best practices. All of ACHC's Surveyors are highly experienced in their respective areas of expertise and hold a sincere interest in helping providers achieve certification while improving their businesses without compromising standards. We are committed to working with the Virginia Board of Pharmacy to provide a viable alternative compliance solution for pharmacies in the state or outside the state of Virginia.

We hope that the information we have provided demonstrates the sincerity of our interest and the value we place on working with the Virginia Board of Pharmacy. If you have any questions or need additional information, please contact Joe Cabaleiro or me directly at (855) 937-2242.

Sincerely,

José Domingos
CEO

VIRGINIA STATE BOARD OF PHARMACY

[PHARMACY CERTIFICATION]

ACHC

FOR PROVIDERS.
BY PROVIDERS.

ACCREDITATION COMMISSION *for* HEALTH CARE

ACCREDITATION COMMISSION
for HEALTH CARE

CONTACTS

José Domingos
CEO
jdomingos@achc.org
T (855) 937-2242 x353

Tim Safley
Director of DMEPOS, Pharmacy, and Sleep
tsafley@achc.org
T (855) 937-2242 x235

Joe Cabaleiro, RPh
Associate Director, Pharmacy
jcabaleiro@achc.org
T (855) 937-2242 x390

855-YES-ACHC (855-937-2242)
139 Weston Oaks Ct., Cary NC 27513

ACHC

FOR PROVIDERS.
BY PROVIDERS.

VIRGINIA BOARD OF PHARMACY

[PHARMACY CERTIFICATION]

TABLE OF CONTENTS

STANDARDS REVISION

The standards included in this submission represent the final, approved version of ACHC's Certification Standards for Sterile and Non-Sterile Compounding. These standards are different from the 'beta' versions previously provided to the Board for the following reasons:

- The intent of these standards is to require compliance with USP<795>, USP<797>, and related standards. During testing, ACHC determined that the standards should reflect the compliance requirements more clearly. In this regard, the enclosed standards are more helpful to pharmacies in achieving the goal of full USP standard compliance. They also more clearly spell out to the Board what ACHC is looking for during a survey.
- The 'beta' standards previously submitted included separate standards for non-sterile and sterile compounding. During our beta testing, we noted this caused confusion and duplicated work. The revised standards incorporate both non-sterile and sterile requirements.
- Our data collection tool was also improved during testing. The standards were revised to reflect the improvements in the tool.

SURVEYOR QUALIFICATIONS AND TRAINING

ACHC currently has 13 Pharmacist Surveyors. All of ACHC's Surveyors have hands-on compounding industry experience in various capacities. For example, ACHC's Surveyor cadre includes:

- Anna Nowobilski-Vasilios PharmD, MBA, FASHP, CNSC, BCNSP — Contributing author: "ASHP Guidelines on Home Infusion Therapy Services"
- Barbara Petroff BS— Contributing Author: "ASHP Guidelines on Home Infusion Therapy Services"
- Roger Klotz RPh, BCNSP, FASCP, FACA, FCPhA— Associate Professor of Pharmacy Practice and Administration, Western University; teaches Sterile Compounding course

ACHC's Surveyors' pharmacy experience ranges from 17 years to 48 years.

ACHC Surveyors receive initial and ongoing training that includes:

- A two-day review of ACHC's Certification Standards, policies and procedures, and processes
- Two precepted surveys
- Annual training to review standard changes, processes and best practices

FOR PROVIDERS.
BY PROVIDERS.

ACHC MISSION STATEMENT & VALUES

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.

ACHC OVERVIEW

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
- Accreditation Programs for Medicare or non-Medicare certification
- Surveys that include an evaluation of adherence to national and state regulations
- Program-specific resources to assist providers throughout the accreditation process
- Accreditation 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
- All-inclusive pricing with no additional fees such as Surveyor travel expenses
- 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 continually 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 and Medicaid Services (CMS)
- Monthly internal audits to ensure continuous compliance and performance improvement

ACHC OVERVIEW

CUSTOMER SERVICE

At ACHC, each employee is dedicated to providing the best possible experience before, during, and after the certification 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 certification 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 certification 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 a certification survey can impact business goals. To help our customers better manage their business operations, ACHC offers a streamlined certification 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 ensures continual accreditation
  - Surveys conducted no later than 60 days prior to accreditation expiration date

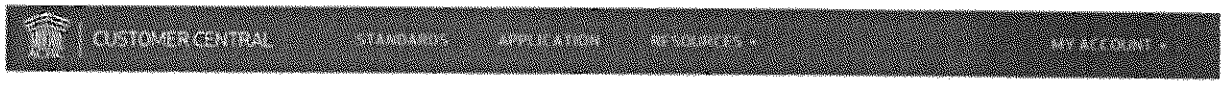
ACHC RESOURCES

As a leading accreditation organization, ACHC believes that continuing education for providers is necessary to achieve the highest quality of patient care. 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 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*
  - Program-specific workbooks that include helpful hints for each standard, process tips, and audit tools for survey preparation

ACHC OVERVIEW

SAMPLE OF WEB PORTAL



Download ACHC's Standards

Select the program and services applicable to your company and click 'Download'. If standards are not required, continue to your application.

Application »

Applying for reaccreditation? Download the program-specific updates under Educational Tools.

Pharmacy

Download

Standards

ACHC Process

ACHC Pharmacy standards are applicable for healthcare organizations that provide services for the preparation, dispensing, and proper utilization of prescription drugs. ACHC Pharmacy standards are customized to meet the individual needs of the provider, including only standards that are relevant to the operations of each specific business. All Pharmacy standards are written by industry experts to align with national regulations. Referring to the descriptions listed below, pharmacies may choose to achieve accreditation, certification, or both. *For Community Retail services, please refer to the Community Retail section.

Accreditation

- ☐ **IRX - Infusion Pharmacy Services (Incl. Sterile Compounding, Ref. USP <797>)**
  Infusion Pharmacy services include IV drug mixture preparation, IV administration, therapy monitoring, client/patient counseling, and education. It is the administration of medications using intravenous, subcutaneous and epidural routes. ACHC Infusion Pharmacy standards include sterile compounding, referencing USP <797>.

- ☐ **SRX - Specialty Pharmacy Services**
  Specialty Pharmacy services dispense medications (injectable, intravenous or oral) to a client/patient home, physician's office, or clinic specializing in certain disease states. These medications target a specific population with a chronic and sometimes life-threatening disease. Specialty Pharmacy includes disease specific clinical monitoring as well as patient compliance and adherence programs.

- ☐ **IRN - Infusion Nursing Services**
  Infusion Nursing services administer parenteral medications via various accesses and ports by a Registered Nurse (RN) specifically trained in these specialized services. This service can be provided in a variety of settings.

- ☐ **AIC - Ambulatory Infusion Center**
  Ambulatory Infusion Center services are centralized locations where a patient can receive infusion therapy administered by the appropriate clinical personnel.

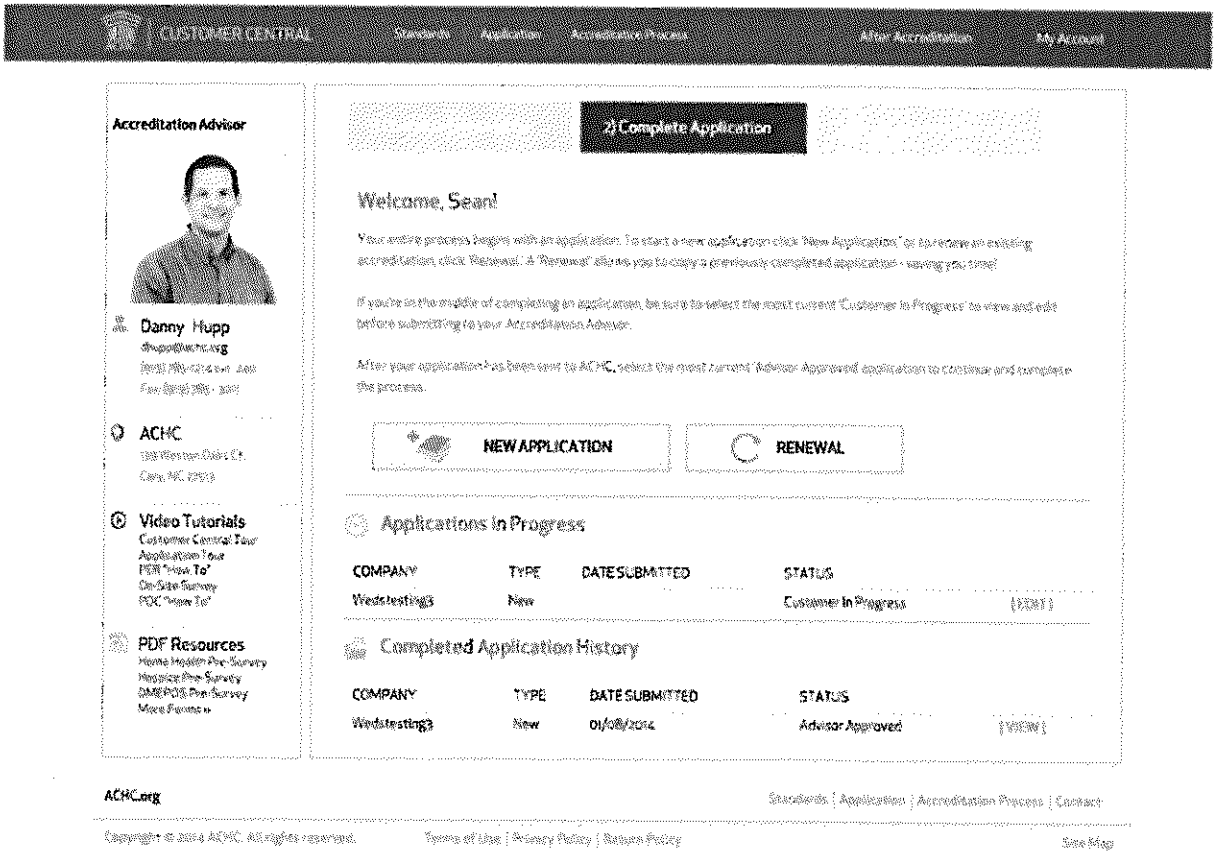
- ☐ **LTC - Long Term Care Pharmacy**
  Long Term Care Pharmacy services manage medications for residents of institutional facilities to ensure proper drug therapy, as well as packaging and delivery of medications.

- ☐ **CFNS - Certification for Non-Sterile Compounding**
  Non-Sterile Pharmacy Compounding is a process by which a pharmacist prepares drugs by combining, mixing, or altering ingredients into a pharmaceutical preparation. These preparations are designed to be administered by a route of administration that does not require sterility as result of a practitioner's prescription drug order. Compounding includes the preparation of drugs in anticipation of receiving prescription drug orders based on routine, regularly observed prescribing patterns. ACHC Certification for Non-Sterile Pharmacy Compounding measures a specific set of process standards that concentrate on the quality and consistency of compounded preparations.

- ☐ **CFST - Certification for Sterile Compounding**
  Sterile Pharmacy Compounding is the practice of preparing sterile medications for patients through strict procedures to prevent contamination and maintain patient safety. ACHC Certification for Sterile Pharmacy Compounding measures a specific set of process standards that concentrate on the quality and consistency of medications that are produced.

ACHC OVERVIEW

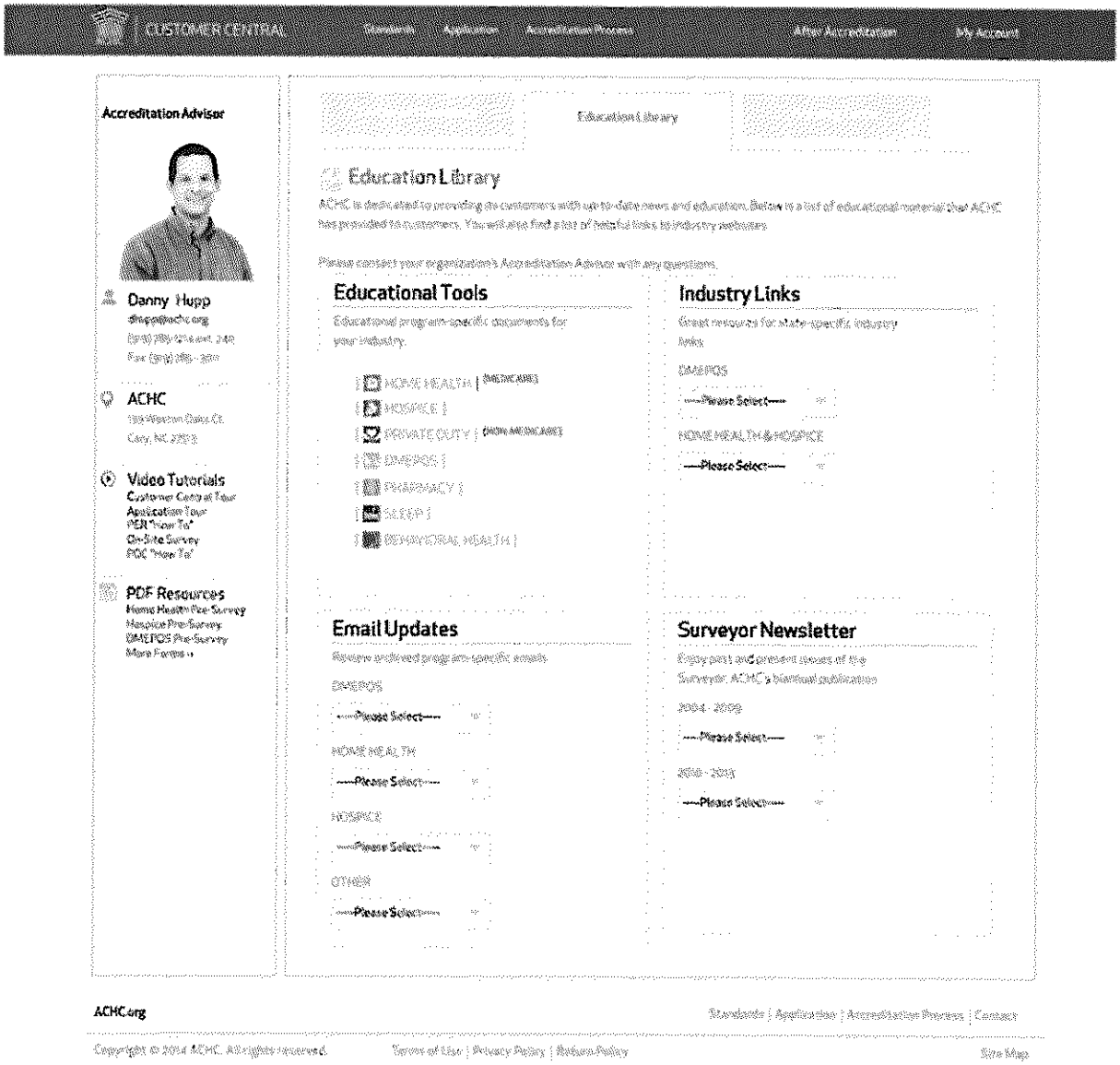
SAMPLE OF WEB PORTAL



52

ACHC OVERVIEW

SAMPLE OF WEB PORTAL



54

PROGRAMS & SERVICES

HOME HEALTH

- **BHHC**—Behavioral Health Home Care
- **HHA**—Home Health Aide Services
- **MSS**—Medical Social Services
- **OT**—Occupational Therapy Services
- **PT**—Physical Therapy Services
- **SN**—Skilled Nursing Services
- **ST**—Speech Therapy Services

HOSPICE

- **HIC**—Hospice Inpatient Care Services
- **HRC**—Hospice Residential Care Services

PRIVATE DUTY

- **PDA**—Private Duty Aide Services
- **PDC**—Private Duty Companion/ Homemaker Services
- **PDN**—Private Duty Nursing Services
- **PDOT**—Occupational Therapy Services
- **PDPT**—Physical Therapy Services
- **PDST**—Speech Therapy Services
- **PDSW**—Medical Social Work

DMEPOS

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

AMBULATORY CARE

Pending beta test*

- **CCC**—Convenient Care Clinics

PHARMACY

- **AIC**—Ambulatory Infusion Center
- **IRN**—Infusion Nursing Services
- **IRX**—Infusion Pharmacy Services
- **SRX**—Specialty Pharmacy Services
- **LTC**—Long Term Care Pharmacy Services
- **CFST**—Certification for Sterile Compounding (Ref. USP <797>)
- **CFNS**—Certification for Non-Sterile Compounding (Ref. USP <795>)

SLEEP

- **SLC**—Sleep Lab/Center Services
- **HST**—Home Sleep Testing

BEHAVIORAL HEALTH

- **CMGT**—Case Management
- **CS**—Community Support
- **DTX**—Day Treatment
- **OTX**—Outpatient Treatment
- **PSR**—Psychosocial Rehabilitation

Available for confirmation survey*

- **ACTT**—Assertive Community Treatment Team
- **ARS**—Assessment and Referral Services
- **IIH**—Intensive In-Home
- **IOTX**—Intensive Outpatient Treatment Services
- **PHS**—Partial Hospitalization Services
- **PSS**—Personal Support Services
- **PVS**—Prevention Services
- **RTX**—Residential Treatment Services
- **SGL**—Supervised Group Living
- **SES**—Supported Employment Services

Pending beta test*

- **BHH**—Behavioral Health Homes
- **CRS**—Crisis Responsive Services
- **FCS**—Foster Care Services
- **ICS**—Integrated Care Services
- **RCS**—Respite Care Services

*An essential component in the validation of ACHC standards is on-site beta testing. Contact ACHC for more information on services that are currently in beta testing.

57

ACCREDITED LOCATIONS

ACCREDITED LOCATIONS BY STATE

April 1, 2014

59

PHARMACY LOCATIONS

ACCREDITED PHARMACY LOCATIONS BY STATE

Revised April, 2014

60

اما

CERTIFICATION PROCESS

ACHC has developed a streamlined process designed to help providers quickly and easily reach their certification goals. Our team of experts follows a partnership approach throughout the entire process to enhance the entire experience and help our customers achieve and maintain certification. The following steps provide a brief overview of the certification process. For a detailed overview of the certification process, refer to the "Policies & Procedures" section (pg. 63).

STEP 1: DOWNLOAD SERVICE-SPECIFIC STANDARDS

ACHC customers have the ability to preview accreditation and certification standards for up to five days at no charge. At any point, they may choose to purchase full access to the standards for the ability to download their customized standards.

STEP 2: SELF-EVALUATION OF PHARMACY PRACTICES TO CERTIFICATION STANDARDS

The pharmacy must complete a thorough self-evaluation of their practices in reference to ACHC certification standards. This provides the opportunity to identify areas for improvement prior to the on-site survey.

STEP 3: COMPLETE APPLICATION & SUBMIT DEPOSIT

ACHC's streamlined application process allows providers to complete the entire application process online. They can provide all of the required information directly through their Customer Central account and submit a deposit to initiate the certification process.

STEP 4: SUBMIT AGREEMENT, PAYMENT, & PRELIMINARY EVIDENCE REPORT (PER)

Once the provider has fully prepared for the survey, they may submit the certification agreement, payment, and PER. At any point during the process, customers have full access to their Accreditation Advisor to help guide them through the process and answer any questions they have.

STEP 5: ON-SITE SURVEY

ACHC will conduct an unannounced on-site survey to assess the compounding process as defined by the non-sterile (ref. USP <795>) and sterile (ref. USP <797>) compounding standards. Each certification survey is conducted by a licensed Pharmacist with compounding expertise.

STEP 6: INITIAL SURVEY RESULTS

ACHC's review committee will analyze the survey results and determine the initial certification decision. The initial decisions include:

- Certified – Provider meets all requirements for full certification status.
- Certification pending – Provider meets basic certification requirements and certification status is granted upon submission of an approved Plan of Correction (POC).
- Dependent – Provider has significant deficiencies and an additional on-site survey will be necessary to be eligible for certification.
- Denied – Certification is denied. Reserved for extremely non-compliant organizations. Reapplication is required.

STEP 7: PLAN OF CORRECTION (POC)

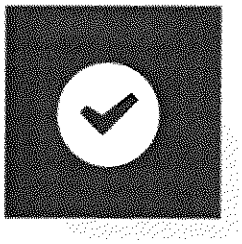
Pharmacies that receive a certification decision of Certified, Certification Pending, or Dependent must submit a POC to ACHC for all deficiencies cited. The POC will include a detailed plan by the pharmacy to correct any deficiencies found during the on-site survey.

STEP 8: FINAL CERTIFICATION DECISION

The pharmacy will receive a final certification decision once all steps are completed, and will receive a certification certificate, if applicable.

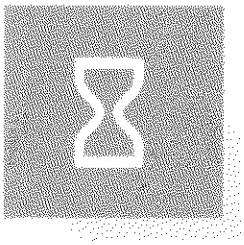
For a complete description of the certification decisions, refer to pages 70-72 of the "Policies & Procedures" section.

CERTIFICATION DECISIONS



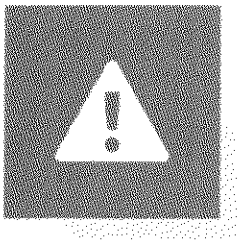
CERTIFIED

Provider meets all requirements for full certification status. Certification is granted but Plan of Correction (POC) may still be required.



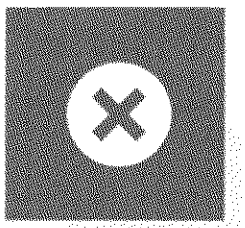
CERTIFICATION PENDING

Provider meets basic certification requirements but certified status is granted upon submission of an approved POC.



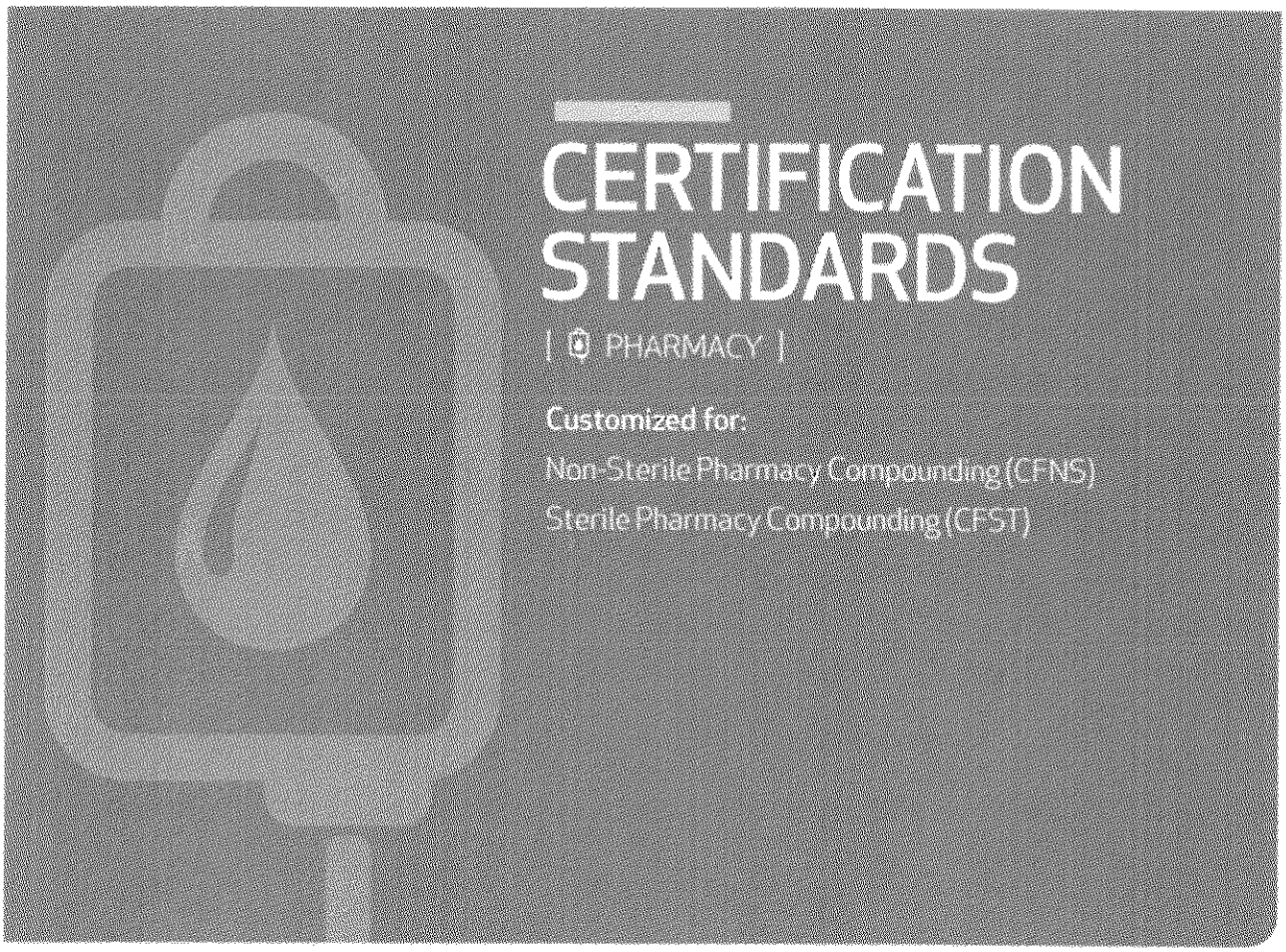
DEPENDENT

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



DENIED

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



CERTIFICATION STANDARDS

| PHARMACY |

Customized for:

Non-Sterile Pharmacy Compounding (CFNS)

Sterile Pharmacy Compounding (CFST)

ACCREDITATION COMMISSION *for* HEALTH CARE

ACHC PHARMACY CERTIFICATION STANDARDS

Customized for:

Non-Sterile Pharmacy Compounding (CFNS)

Sterile Pharmacy Compounding (CFST)

ACHC CERTIFICATION STANDARDS

Customized for Certification of Non-Sterile Compounding, Certification of Sterile Compounding

Section 1-C: Certification 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.

ACHC certification 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.

ACHC Certification 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 pharmacy.

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

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

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

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

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 who are certified 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 certification. (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 Non-Sterile Compounding Certification requirements.

The following documentation is submitted to ACHC two months prior to the expiration of the organization's certification. 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 who are certified 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 certification. (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 Sterile Compounding Certification requirements.

The following documentation is submitted to ACHC two months prior to the expiration of the organization's certification. 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

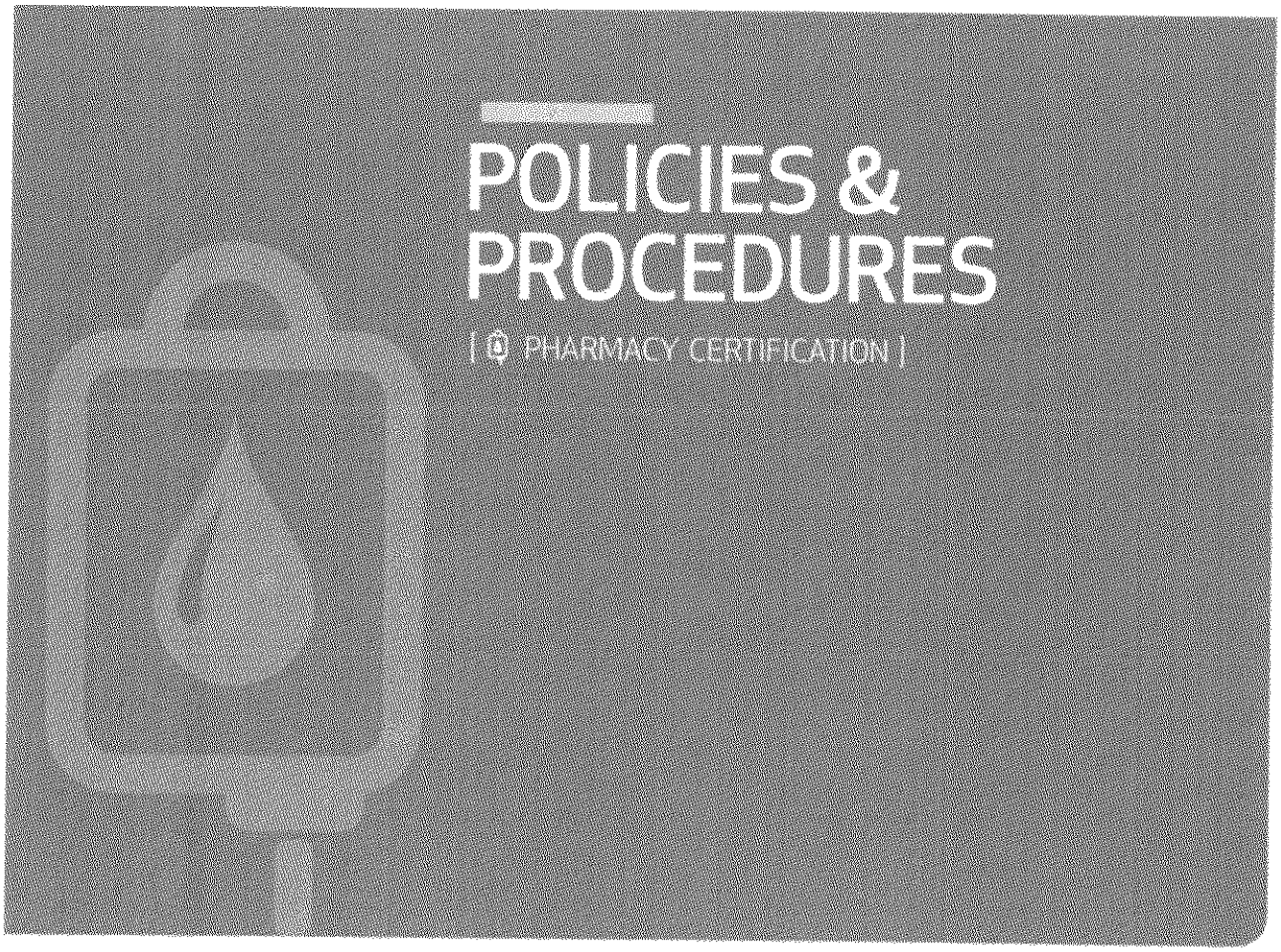
Appendix A: Standard Service Table for Selected Services

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

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	



ACCREDITATION COMMISSION *for* HEALTH CARE

I. Introduction

The Accreditation Commission for Health Care, Inc. (ACHC) is an independent, 501(c)(3) non-profit accrediting organization, which is certified to ISO 9001:2008 standards. ACHC is governed by a volunteer Board of Commissioners (Board), which is composed of health care professionals and consumers. The policies and procedures contained in this document pertain to all organizations, whether they are applying for Certification for the first time, renewing Certification, adding or eliminating branches, or adding or eliminating services. As a result of changes in industry standards and/or regulatory changes, as well as ACHC's continuous internal review of its processes, ACHC may update its Certification Policies and Procedures. Accordingly, ACHC's services will be furnished in accordance with the most current version of the ACHC Certification Policies and Procedures in effect on the date of the survey or in effect at the time of any other activity.

II. Requirements

A. Eligibility Requirements

The organization may apply for Certification if the following eligibility requirements are met.

The organization must:

1. Be licensed according to applicable state and federal laws and regulations and maintain all current legal authorization to operate.
2. Occupy a building in which services are provided/coordinated that is identified, constructed, and equipped to support such services.
3. Submit all required documents and fees to ACHC within specified time frames.

B. ACHC Pharmacy Certification Services

1. Pharmacy Program

a. **Sterile Pharmacy Compounding, ref. USP <797> (CFST):** Sterile Pharmacy Compounding is the practice of preparing sterile medications for patients through strict procedures to prevent contamination and maintain patient safety. ACHC Certification for Sterile Pharmacy Compounding measures a specific set of process standards that concentrate on the quality and consistency of medications that are produced.

b. **Non -Sterile Pharmacy Compounding, ref. USP <795> (CFNS):** Non-Sterile Pharmacy Compounding is a process by which a pharmacist prepares drugs by combining, mixing, or altering ingredients into a pharmaceutical preparation. These preparations are designed to be administered by a route of administration that does not require sterility as result of a practitioner's prescription drug order. Compounding includes the preparation of drugs in anticipation of receiving prescription drug orders based on routine, regularly observed prescribing patterns.

III. Principles Governing the Certification Survey

A. Compliance

During the Certification survey, ACHC determines whether the organization is meeting the intent of the ACHC Standards for Certification. Proof of compliance is based upon items such as:

a. Review of Master Formulary Records
b. Personnel files
c. Policies and procedures
d. On-site observations
e. Interviews

It is the organization's responsibility to ensure compliance with the ACHC Certification Standards at all times during the Certification period.

B. Education

While the organization is preparing for its survey, the organization's Accreditation Advisor is available to provide assistance with the Certification process. Clinical Managers are available for interpretation of ACHC Standards for Certification or suggestions on how to implement them. During the survey, ACHC surveyors will provide education and "best practice" suggestions to help the organization achieve optimum performance.

C. Types of Surveys

1. **Initial Certification Survey*:** An Initial Survey is conducted on organizations which apply for ACHC Certification for the first time. Initial Surveys are unannounced.
2. **Renewal Certification Survey*:** A Renewal Survey is conducted on organizations that are currently certified by ACHC. Renewal Surveys are conducted in the same format as an Initial Survey; however, during the Renewal Survey, the surveyor also reviews previous deficiencies for compliance. Renewal Surveys are unannounced.
3. **Dependent Survey:** A Dependent Survey is a re-survey conducted on an organization that was not in compliance with ACHC Certification Standards. Dependent Surveys are unannounced.
4. **Focus Survey:** A Focus Survey is conducted on organizations to ensure ongoing and continued compliance with the ACHC Certification Standards. Focus Surveys can take place anytime throughout the Certification period or for any organizational changes. Focus surveys are unannounced.
5. **Complaint Survey:** A Complaint Survey is conducted on organizations that have a complaint filed against them. Should ACHC determine during the investigation that a site visit is required, ACHC will conduct a Complaint Survey. Complaint Surveys are unannounced.
6. **Disciplinary Action Survey:** A Disciplinary Action Survey is conducted on organizations that are placed Under Review (Section VII, A) due to non-compliance from a previous survey, the ACHC Standards for Certification and/or these Policies and Procedures. Disciplinary Action Surveys are unannounced.

* **Full Survey:** This is a comprehensive survey examining all of the ACHC Certification Standards.

IV. Certification Process before the Survey

A. Register for access to ACHC through Customer Central

1. Access Customer Central through the ACHC website (www.achc.org).
2. Create username and password.
3. Receive Accreditation Advisor's contact information.

B. Download ACHC Certification Standards

1. Available for organizations that have not previously obtained them.
2. Once purchased, organization has unlimited access to all ACHC Standards.
3. Credit is applied for organizations that submit a deposit for Certification.

C. Complete ACHC Certification Application and Submit Deposit

1. Complete online Certification Application in its entirety. (Paper format is available).
2. Complete statistical information for all physical locations. Based on governance, complexity of corporate structure, tax reporting, and other factors, ACHC will determine the number of applications and number of surveys required.
3. Submit non-refundable deposit (applied toward certification fee).

D. Execute Agreement for Certification Services

1. The Agreement for Certification Services and the Business Associate Agreement (BAA) outline the obligations of both ACHC and the organization.
2. Sign and return the Agreement and BAA to ACHC within the specified time frames listed on the cover page.
3. Failure to meet any terms of the Agreement or BAA may result in rescheduling or cancellation of the survey with fees assessed.

E. Submission and Review of Preliminary Evidence Report (PER)

1. Attestation on PER checklist is completed confirming existence of required policies and procedures.
2. Upload required PER checklist and documents through Customer Central (Contact Accreditation Advisor if organization is unable to submit electronically).
3. ACHC evaluates the content of all required documents and the ACHC surveyor will discuss any questions with the organization during the onsite visit.
4. A review of all Policies and Procedures related to the ACHC Certification Standards is available to organizations for a fee.

F. Scheduling

1. Upon receipt of the required PER documents, the scheduling process is initiated.
2. Organizations are allowed to choose up to 10 black-out days on which ACHC will not schedule a survey. Only two of these days can be Wednesdays. (Please note, choosing fewer black-out dates provides greater flexibility in scheduling the survey.)
3. The following days do not need to be included in the organization's black-out days:
   a. New Year's Day

b. Good Friday
c. Memorial Day
d. Independence Day
e. Labor Day
f. Thanksgiving Day and the following day
g. Christmas Eve
h. Christmas Day

4. ACHC reserves the right to send a surveyor preceptee as part of the survey team. A preceptee is sent at no charge to the organization. All ACHC surveyors/preceptees must disclose any potential conflict of interest with the organization to ACHC before they are assigned to conduct the survey. Surveyors/preceptees with a confirmed conflict are not utilized for the survey being scheduled.

G. Postponement of Survey

1. Organizations may postpone an ACHC survey as long as the ACHC surveyor has not begun to travel to the organization's location. Postponements must be requested in writing to the organization's Accreditation Advisor using the ACHC Postponement Form. ACHC will invoice a postponement fee as listed in the Agreement for Certification Services.
2. The organization is responsible for notifying the Accreditation Advisor in writing of its readiness for survey within 180 days from receipt of the ACHC Postponement Form. If the organization notifies the Accreditation Advisor within the specified timeframes, the organization will be scheduled for a survey following the ACHC scheduling process. If the organization does not notify the Accreditation Advisor within the specified timeframes, the organization's deposit will be forfeited, application voided, and the organization must re-apply for Certification.

V. Certification Survey Process

A. Certification Survey Day

1. **Opening Conference:** The opening conference may consist of the following based on the organizational structure:
   a. Introduction of the surveyor(s)
   b. Review of the tentative schedule
   c. Review questions on any documents from the application process
   d. Q&A from the organization about the survey
2. **Tour of the organization**
3. **Data Collection**
   a. In order for ACHC to ensure that the organization is compliant with all ACHC Certification Standards, the survey focuses on the following:
      i. Personnel record review
      ii. Product record review
      iii. Risk management

iv. Performance Improvement activities
v. Onsite observations
vi. Personnel interviews

4. **Closing Conference**

During the closing conference the surveyor discusses survey findings While the organization's personnel are given the opportunity throughout the survey to provide information that does not appear readily available to the surveyor, the closing conference provides representatives of the organization a final opportunity to clarify information or present data that may not have been reviewed by the surveyor during the survey. The surveyor does not render judgment as to whether the organization will be granted Certification. The surveyor's role is to review information presented and to clarify, observe, and verify data that supports compliance with applicable ACHC Certification Standards.

B. Refusal of Survey

1. Organizations have the right to refuse an ACHC survey. In the event a refusal is requested, the organization must speak to the Accreditation Advisor or an appropriate manager at ACHC to request a Survey Refusal Form. A completed Survey Refusal Form must be submitted to ACHC before the surveyor can leave the location. If an ACHC surveyor arrives on-site and the organization does not meet the eligibility criteria for a Certification survey, the organization must refuse the survey and complete a Survey Refusal Form.
2. If an ACHC surveyor arrives on-site and the organization is not operating during its posted business hours, the surveyor will notify the ACHC Accreditation Advisor and leave the location. This will be considered a refusal of survey.
3. The organization is charged a refusal fee as listed in the Agreement for Certification Services. The organization is responsible for notifying the Accreditation Advisor in writing of its readiness for a resurvey following the timeframes as detailed in the Agreement for Certification Services. If the organization notifies the Accreditation Advisor within the specified timeframes as detailed in the Agreement for Certification Services, the organization will be sent to scheduling and will follow the normal scheduling process. If the organization notifies the Accreditation Advisor outside of the specified timeframes as detailed in the Agreement for Certification Services, the organization's deposit will be forfeited, application voided and the organization must re-apply for Certification.

VI. Certification Process Post Survey

A. Reviewing the Data Collected

1. **Scoring:** Following the conclusion of the Certification survey, the ACHC surveyor will submit all of the data collected to the organization's Accreditation Advisor for processing. The information is entered into an electronic tool which provides objective data for determining the Certification decision.
2. **Preparing the Summary of Findings:** The Summary of Findings is prepared detailing all ACHC Certification Standards that was marked as a deficiency during the Certification survey. Each ACHC Standard for Certification marked as a

deficiency will contain an "Action Required" statement. This will assist the organization in preparing a Plan of Correction (POC) to meet the ACHC Certification Standards. Surveyors may include any "Best Practice" suggestions in their summary as additional education. These best practice suggestions are not mandatory for the organization but are recommendations for improvement.

3. **Certification Review:** All Summary of Findings that result in a denial decision are analyzed by the appropriate Clinical Manager or designee and evaluated by a minimum of one other appropriate individual to ensure consistency before the denial decision is rendered.

B. **Certification Decisions**

1. **Approval of Certification:**
   a. Certification is Approved based on the following criteria:
      i. Results of the data collected during survey
      ii. Number and/or severity of deficiencies
      iii. Clinical Manager/designee review
   b. A Plan of Correction (POC) is required for any ACHC Certification Standards not fully met. The POC is due to ACHC within 30 days from the date of the organization's Approval letter with necessary supporting documentation. A Certificate of Certification will not be sent to the organization until the Plan of Correction (POC) has been approved by ACHC.
   c. The Certification effective date for new and renewal organizations that receive an Approval of Certification is determined as follows:
      i. **New Organizations:** The Certification effective date is the last day of survey.
      ii. **Renewal Organization:** The Certification effective date will continue for an additional 12 months from the expiration if the organization shows proof of on-going compliance with the ACHC Certification Standards.
2. **Certification Pending:**
   a. Certification Pending is based on the following criteria:
      i. Results of the data collected during survey
      ii. Number and/or severity of deficiencies
      iii. Clinical Manager/designee review
   b. A Plan of Correction (POC) is required for any standards not fully met. The POC is due to ACHC within 30 days from the date of the organization's Certification Pending letter with necessary supporting documentation. Failure to submit evidence may result in the organization being designated as Under Review (Section VII, A).
   c. All POCs are reviewed by the Clinical Manager/designee. After reviewing the POC ACHC may:
      i. Approve POC and grant Certification
      ii. Reject POC and require additional information

iii. Move an organization into Dependent Status (Section VI, B, 3)

d. Following the review of the POC, if Certification is granted, the effective dates for new and renewal organizations are determined as follows:

i. **New Organizations:** The effective date is the day the approved Plan of Correction is received by ACHC. An approved POC is one that has been accepted by the Clinical Manager/designee.

ii. **Renewal Organization:** The Certification effective date will continue for an additional 12 months from the expiration if the organization shows proof of on-going compliance with the ACHC Certification Standards.

3. **Dependent Status:**

a. Dependent Status is determined based on the following criteria:

i. Results of the data collected during survey

ii. Number and/or severity of deficiencies

iii. Clinical Manager/designee review

b. The POC is due to ACHC within 30 calendar days from the date of the Dependent Status letter. The organization must submit written notification to ACHC of its readiness for a Dependent Survey, at the organizations expense, within 90 days of the date of the dependent letter. If the organization fails to notify ACHC within 90 days, the decision will move to a Denial of Certification.

c. The surveyor submits the findings from the Dependent Survey to the organization's Accreditation Advisor and a decision will be made by the Clinical Manager/designee. Upon review ACHC may:

i. Grant Certification

ii. Issue a Certification Pending

iii. Deny Certification (Section VI, B, 4)

d. Following a Dependent Survey, if Certification is granted, the effective Certification dates for new and renewal organizations are determined as follows:

i. **New Organizations:** The effective date of Certification is the last day of the Dependent Survey if no deficiencies are identified. If deficiencies are identified during the Dependent Survey, the effective date of Certification is the day the approved POC is received by ACHC from the Dependent Survey. An approved POC is one that has been accepted by the Clinical Manager/designee.

ii. **Renewal Organization:** The Certification effective date will continue for an additional 12 months from the expiration if the organization shows proof of on-going compliance with the ACHC Certification Standards.

4. **Denial of Certification:**

a. Certification is Denied based on the following factors:

i. Results of the data collected during survey

ii. Number and/or severity of deficiencies
iii. A minimum of two Clinical Manager/designees review decision

b. If Certification is Denied, the organization has the option to appeal the decision by following the steps outlined in the Appeals Process (Section VI, E)

c. If Certification is Denied, the organization has the opportunity to re-apply for Certification at any time they are ready for survey. At the time of re-application, a new application must be submitted with a non-refundable deposit and a PER. The organization has the option to submit a new PER or request that ACHC use the PER on file. If the organization elects to use the PER on file, it must notify the Accreditation Advisor in writing. Upon receipt of an organization's application for survey as a result of a Denial of Certification, the application will be processed in the order it was received. ACHC does not expedite any part of the Certification process for an organization that has received a Denial of Certification.

C. Certification Documentation

1. Once a Certification decision is made by the Clinical Manager/designee the Certification decision is given to the Accreditation Advisor. The Accreditation Advisor then prepares the proper documentation to send to the organization.
2. Based on the Certification decision, the Accreditation Advisor sends the following:
   a. Approval of Certification with No Deficiencies: Certification Approval letter, Certificate of Certification, state form, Summary of Findings, and window decal
   b. **Approval of Certification with Deficiencies:** Certification Approval letter, state form, Summary of Findings, and Plan of Correction Template
      i. Certificate of Certification and window decal will be sent to the organization when the completed POC is approved by ACHC
   c. **Certification Pending:** Certification Pending letter, state form, Summary of Findings, and Plan of Correction Template
   d. **Dependent Status:** Dependent Status letter, Summary of Findings, and Plan of Correction Template
   e. **Denial of Certification:** Denial letter and Summary of Findings
3. The POC must be completed in its entirety, returned to ACHC and approved by the Clinical Manager/designee in order to be acceptable. The POC must be completed on the ACHC Plan of Correction Template and must contain the following elements:
   a. The standard that was out of compliance
   b. Corrective action to be taken
   c. Implementation date
   d. Title of individual responsible
   e. Process for continued compliance
4. Once an organization receives an Approval decision, the organization's Certification information can be found on the ACHC website for verification.

D. Dispute Process

Organizations, whether applying for the first time or renewing their certification, may formally request to dispute a standard(s) deficiency documented on the Summary of Findings. If a company wants to dispute a denial decision, they must follow the appeal process (refer to Section VI. E).

The procedure to dispute a standard(s) deficiency is as follows:

1. The organization submits a written request for dispute to its ACHC Accreditation Advisor no later than 30 calendar days from the receipt of the Summary of Findings. Requests received after the 30 calendar day timeframe are not granted.
2. The written request outlines the standard(s) noted in the Summary of Findings that the organization believes ACHC incorrectly determined as a deficiency. The organization must also provide evidence to support that, at the time of the survey, the organization was in compliance with the standard(s). Any evidence the organization submits must have been presented to and reviewed by the surveyor(s) at the time of the survey. Evidence provided with the request letter will not be returned to the organization.
3. Upon receipt of the request for a dispute, ACHC sends an acknowledgement letter to the organization
4. If the organization is required to submit a Plan of Correction (POC) as a result of their survey, the organization must indicate on the POC any standard(s) deficiency being disputed.
5. The ACHC Review Committee will evaluate and determine whether ACHC followed its stated Policies and Procedures in conducting the organization's certification survey.
6. Any ACHC Review Committee member who has a conflict of interest with the organization under review refrains from voting on the dispute.
7. Upon completion of the review, the ACHC Accreditation Advisor notifies the organization of the ACHC Review Committee's decision to either uphold or reverse the original standard(s) deficiency noted on the Summary of Findings.
8. All decisions made by the ACHC Review Committee are final.

E. Appeal Process

Organizations, whether applying for the first time or renewing their Certification, may formally request to appeal a Denial decision. The procedure to appeal a Denial of Certification is as follows:

1. The organization submits a written request for appeal to its ACHC Accreditation Advisor no later than 30 calendar days from the date on ACHC's Denial letter. Requests received after the 30 calendar day timeframe are not granted.
2. The written request outlines the standard(s) noted in the Summary of Findings that the organization believes ACHC incorrectly determined as a deficiency. The organization must also provide evidence to support that, at the time of the survey, the organization was in compliance with the standard(s). Any evidence the organization submits must have been presented to and reviewed by the surveyor(s) at the time of the survey. Evidence provided with the request letter will not be returned to the organization.

3. Upon receipt of the request for an appeal, ACHC sends an acknowledgement letter to the organization.
4. The ACHC Appeals Committee is composed of a minimum of three individuals who have clinical and/or program expertise will evaluate and determine whether ACHC followed its stated Policies and Procedures in conducting the organization's Certification survey.
5. Any ACHC Appeals Committee member who has a conflict of interest with the organization under review refrains from voting on the appeal.
6. Upon completion of the review, the ACHC Accreditation Advisor notifies the organization in writing of the ACHC Appeals Committee's decision to either uphold or reverse the original Denial decision.
7. All decisions made by the ACHC Appeals Committee are final.

F. Continued Compliance

1. Certification is contingent upon continued compliance with the ACHC Certification Standards and the Certification Policies and Procedures. After an organization is granted Certification, ACHC reserves the right to make unannounced Focus Survey visits at any time during the Certification period to ensure continued compliance with the ACHC Certification Standards.
2. Organizations that have been issued Certification will be required to submit annual verification of compliance. ACHC will review the submitted information and will make the determination whether Certification will continue for an additional 12 months.

G. Renewing Certification

1. Certification is not automatically renewable. ACHC will issue the organization an updated Agreement for Certification Services. Once the agreement is executed, ACHC will put the organization into scheduling.
2. In the event an organization's Certification expires, the organization's Certification information will be removed from the certified organization list located on the ACHC website.

VII. Disciplinary Actions as a Result of Survey Findings:

Disciplinary actions can result as a consequence of the following surveys: Dependent Survey, Focus Survey, Complaint Survey and CHOW Survey. Failure to remain in compliance with the ACHC Certification Standards or these Policies and Procedures may result in a disciplinary action. The organization may be billed for surveys conducted which resulted in a disciplinary action. The following disciplinary action statuses are possible:

A. Under Review

1. The organization's Certification can be placed Under Review when ACHC has sufficient evidence that non-compliance with the ACHC Certification Standards and/or these Policies and Procedures has occurred. In particular, ACHC will review the nature, severity, and scope of the non-compliance and the degree of harm or potential for harm to patients. ACHC also will review the organization's service

performance, prior history of compliance with the ACHC Certification Standards and/or these Policies and Procedures.

2. The organization is required to formulate and return a Plan of Correction for deficiencies within 10 calendar days of the notification letter. The Certification Review Committee will review the submitted documentation and render a decision on whether to continue or terminate the organization's Certification. A Disciplinary Action Survey may be required to ensure that all corrective actions have been initiated.

B. Termination

Following a status of Under Review, ACHC will determine if an organization's Certification will be terminated. Termination entails loss of an organization's Certification and may include notification to the appropriate regulatory agencies including CMS. Organizations may apply for Certification when they feel ready. Termination decisions are considered public record and will be reported to all appropriate parties. The organization will be removed from all listings of ACHC certified sites.

VIII. Notification of Changes

ACHC requires organizations to provide the required documentation described below within thirty (30) days of a change occurring. Changes include branch office addition or deletion, service addition or deletion, change in the name, location, ownership or control of the organization. Failure to submit the required documentation within the thirty (30) day timeframe may result in a gap in Certification.

A. Name Changes

1. If an organization goes through a name change, the organization must notify ACHC of the change via a notification letter and additional documentation. The organization's notification letter and additional documents must include the following:
   a. Effective date of the change
   b. Former name, as well as new legal name
   c. Photographs of the following:
      i. Outside of building with signage with new name
      ii. Posted hours of operation
      iii. Interior office and/or retail space
      iv. Warehouse (if applicable)
   d. Include copies of all licenses with new name
2. ACHC may request additional documentation upon review. If approved, ACHC will issue a new Certification certificate.
3. If it is determined a site survey is necessary, the normal unannounced survey scheduling process will apply and the organization is charged a survey fee. If it is determined a survey is not necessary, the organization is charged a prorated fee based on the length of remaining Certification.
4. If the organization is found to have substantial deficiencies during the site survey, the Certification for that location and/or the organization as a whole is reviewed by

the Clinical Manager/designee and the Certification Review Committee. Following the review, the organization may be placed in Under Review.

B. Location Change

1. If an organization goes through a location change, the organization must notify ACHC of the change via a notification letter and additional documentation. The organization's notification letter and additional documents must include the following:
   a. Effective date of the change
   b. Former address and new address
   c. Photographs of the following:
      i. Outside of building with signage
      ii Posted hours of operation
      iii. Interior office and/or retail space
      iv. Warehouse (if applicable)
   d. Include copies of all licenses with new address
2. ACHC may request additional documentation upon review. If approved, ACHC will issue a new Certification certificate for any address changes outside the original city and state.
3. If it is determined a site survey is necessary, the normal unannounced survey scheduling process will apply and the organization is charged a survey fee. If it is determined a survey is not necessary, the organization is charged a prorated fee based on the length of remaining Certification.
4. If the organization is found to have substantial deficiencies during the site survey, the Certification for that location and/or the organization as a whole is reviewed by the Clinical Manager/designee and the Certification Review Committee. Following the review, the organization may be placed in Under Review.

C. Cessation or Interruption within the Organization

1. If the organization has a cessation or interruption of all the organization's operations, offering of service and/or a deletion of any service that has received Certification, the organization must notify ACHC via a notification letter. The organization's notification letter to ACHC must include the following:
   a. Effective date of the cessation or interruption
   b. Detailed description of the reason for the cessation or interruption
2. Upon receipt of the written notification, ACHC will review and send an acknowledgment to the organization. The notification letter is placed in the organization's file. ACHC may request additional documentation before an acknowledgement letter is sent.
3. The organization notifies ACHC of any change in the status from the acknowledgment of the cessation or interruption of operations. Upon notification, ACHC will review the organization's Certification status and determine if a site visit is required to ensure compliance with the ACHC Certification Standards.

D. Merger/Ownership Changes

1. The following process is followed when an organization has a merger/ownership change, such as:
   a. Stock Transfer
   b. Asset Purchase
   c. Acquisition
   d. Merger
   e. Consolidation
2. The following information is submitted to the organization's ACHC Accreditation Advisor for review by the appropriate manager/designee. Organizations are to report any ownership changes of 5% or greater.
   a. Letter of attestation which includes:
      i. Type of change (e.g., Acquisition, Merger, etc.)
      ii. Detail of all changes including new management and/or owner
      iii. Proposed date of change
      iv. Statement that policies and procedures are not changing, or, if they are changing, what are the specific changes
      v. List old and new federal tax ID number and NPI number (if applicable)
      vi. Who the new contacts will be, including: owner; leader; liaison; and the phone numbers and email addresses for each

   b. Documentation which includes:
      i. Completed statistical data form
      ii. New organizational chart
      iii. Copy of the bill of sale
      iv. Business/state licenses (if applicable)
      v. State form
3. A review of the documentation is performed and any missing information is requested from the organization in writing. ACHC holds the documentation without further processing until the missing information is received from the organization. Once all required documentation has been submitted, the appropriate Clinical Manager/designee reviews the submitted documentation and a Certification decision is made whether a site survey is warranted.
4. Upon approval of the submitted documentation, ACHC issues Certification based on the date that all required documentation was submitted. If the documentation is submitted prior to the effective date, the approval date will begin on the date of the change. All fees must be paid in full before ACHC issues any Certification documentation.
5. If it is determined a site survey is necessary, the normal unannounced survey scheduling process will apply and the organization is charged a survey fee. If it is

determined a survey is not necessary, the organization is charged a prorated fee based on the length of remaining Certification.

6. If the organization is found to have substantial deficiencies during the site survey, the Certification for that location and/or the organization as a whole is reviewed by the Clinical Manager/designee and the Certification Review Committee. Following the review, the organization may be placed in Under Review.

IX. Public Information

A. Logo/Advertising Language

An organization must accurately describe only the program(s), service(s) and branch office(s) currently certified by ACHC and abide by the ACHC Logo Usage Guidelines when displaying Certification status using ACHC's logos or ACHC's name. False or misleading advertising represents noncompliance with ACHC Certification Policies and Procedures and will result in penalties up to and including termination of Certification. The ACHC Logo Usage Guidelines are available on the organization's Customer Central website. Branch programs and services accredited during the Certification cycle cannot be advertised as certified until appropriate Certification certificates are issued by ACHC.

B. Press Releases

ACHC encourages organizations to publicize their Certification status. Publicity tips and a sample press release are available to approved organizations on their Customer Central website.

X. Nonconformance Policy

A. Handling of Complaints

As required by ACHC Certification Standards, accredited organizations must provide ACHC's telephone number to their clients/patients as part of their patient informational material for purposes of reporting a complaint. If complaints cannot be resolved through the organization's complaint process, patients may file a complaint with ACHC. These complaints should identify facts or circumstances that relate to the complaint. ACHC documents and investigates all complaints/allegations received against currently accredited organizations. ACHC follows CMS Complaint Procedure guidelines for conducting investigations and records of complaints are maintained. ACHC will investigate and maintain records on complaints from any source when an ACHC certified organization appears to be out of compliance with its ACHC Certification Standards.

1. Complaint Should Include:
   a. Name, mailing address and phone number of the person filing the complaint
   b. Name of the organization involved
   c. A detailed description of the incident that is the subject of the complaint, including identification of date, time, and location of each incident, as well as the identity of other individuals with information about the incident.
2. While under investigation by ACHC, a complaint is a confidential matter. However, ACHC cannot guarantee complainants that their identity will remain confidential if

the organization determines the identity based on their own internal methods/investigation.

B. Processing a Complaint

ACHC will determine the severity and urgency of the allegations so that appropriate and timely action can be taken. Comprehensive information is collected during the Intake Process. Quality Assurance or an appropriate designee enters pertinent information into the complaint database and then discusses the complaint with the appropriate Clinical Manager who is professionally qualified to evaluate the allegations to ensure that patients are not in danger of abuse, neglect, exploitation, inadequate care or supervision.

C. Immediate Jeopardy (IJ)

IJ is defined as: "A situation in which the provider's noncompliance with one or more requirements of participation has caused, or is likely to cause, serious injury, harm, impairment, or death to a patient." (42 CFR Part 489.3) Complaints are assigned this priority if the alleged noncompliance indicates there was serious injury, harm, impairment or death of a patient or resident, or the likelihood for such, and there continues to be an immediate risk of serious injury, harm, impairment or death of a patient or resident unless immediate corrective action is taken. The identification and removal of IJ, either psychological or physical, are essential to prevent serious harm, injury, impairment, or death for individuals.

1. In accordance with the Medicare State Operations Manual Appendix Q, ACHC acknowledges the following principles of IJ, including:
   a. Only one individual needs to be at risk. Identification of IJ for one individual will prevent risk to other individuals in similar situations.
   b. Serious harm, injury, impairment, or death does not have to occur before considering IJ. The high potential for these outcomes to occur in the very near future also constitutes IJ.
   c. Individuals must not be subjected to abuse by anyone including, but not limited to the organization's personnel, consultants or volunteers, family members or visitors.
   d. Serious harm can result from both abuse and neglect.
   e. Psychological harm is as serious as physical harm.
   f. When a surveyor has established through investigation that a cognitively impaired individual harmed an individual receiving care and services from the organization due to the organization's failure to provide care and services to avoid physical harm, mental anguish, or mental illness, this should be considered neglect.
   g. Any time a team cites abuse or neglect, it should consider IJ.
2. ACHC will conduct an unannounced survey on the organization to investigate the issues within two business days of receipt of the allegations.
3. If Immediate Jeopardy has been identified, a verbal notice is given to the entity, including the specific details and individuals at risk. If corrective measures have not already been implemented, the entity should begin immediate removal of the