

FALL/WINTER 2021



FOR PROVIDERS.
BY PROVIDERS.



Quality Review Edition

THE SURVEYOR

 PHARMACY

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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.



CORNER VIEW

In the fall of 2020, ACHC merged with the parent company of the first U.S. healthcare accreditation program, HFAP. The merger added CMS-deemed accreditation for facility-based care including acute care hospitals, ambulatory surgery centers, clinical laboratories, critical access hospitals; non-deemed accreditation for office-based surgery; and certification for stroke care, wound care, joint replacement, and lithotripsy to ACHC's existing portfolio of community-based accreditation and education programs.

Part of the assimilation process has been to audit our distinct resources in order to bring the very best from each separate entity to our new, unified company. You are reading one result of

While healthcare is constantly evolving, we are currently emerging from a time of unusually rapid change.

that exercise. **The Surveyor** is an ACHC legacy publication, but the Fall/Winter edition now parallels what was previously HFAP's annual **Quality Review**. That publication examined the most frequently cited deficiencies for each accreditation program to give organizations a tool for benchmarking and improving their performance.

In years past, ACHC identified frequent deficiencies by program and made them available annually as a "top ten" list. Now, using **The Surveyor** to share the data gives us a vehicle to add value by deepening the analysis. This is presented in separate editions for closely

affiliated programs. You can access any of them on our website (achc.org) under Resources and Education/Publications.

As you review the edition or editions most relevant to your setting, you will read examples of actual survey findings. These serve to clarify the specific aspects of the standard that were found to be non-compliant. Following the sample citations, you'll find tips for compliance.

While healthcare is constantly evolving, we are currently emerging from a time of unusually rapid change. Some of the deficiencies cited in the following pages can be traced directly to the impact of COVID-19. Many organizations made significant adjustments to continue to meet the needs of their patient/client populations: adopting new technology for remote visits and patient monitoring; sourcing against PPE shortages; reassigning staff to manage furloughs and quarantines. These are all examples of unanticipated change that required quick action that may have shifted focus away from some areas of required compliance.

Organizations that previously received the HFAP **Quality Review** used it in conjunction with their Deficiency Report (ACHC's Summary of Findings) to compare their performance against peer organizations and to proactively address issues frequently seen in other organizations. Used this way, the data becomes part of the process of continuous quality improvement and on-going survey readiness. We want to help you avoid a series of ramp up activities as your survey approaches by making ACHC Standards part of your overall quality strategy.

As always, ACHC is here as a partner in meeting your accreditation and education needs. Your feedback on this publication and on any aspect of our programs is welcomed and invited.

José Domingos
President & CEO

ACHC pharmacy services and distinctions are intentionally designed to parallel pharmacy specialties reflecting the range from community retail settings to hospital-based or independent sterile compounding pharmacies.

FROM THE PROGRAM DIRECTOR

Evaluating frequently-cited deficiencies offers a data-driven review of survey results for ACHC-accredited pharmacies. It helps guide our efforts to provide relevant, actionable education for the organizations that look to ACHC for leadership in establishing and evaluating quality.

The data in this report reflect deficiencies cited on surveys performed between June 1, 2020, and May 31, 2021. The data are presented in two sections specific to the requirements for PCAB (compounding) accreditation and for all other pharmacy services. Not included are deficiencies in standards related to ACHC Distinction recognitions. For this period, I have been impressed overall with how pharmacies have responded to the COVID-19 pandemic as absolute heroes while maintaining a high level of compliance. That commitment to quality is remarkable.

While we are identifying those standards that are most frequently “missed” by organizations, the overall incidence for each is low as noted in the narrative that follows. More and more pharmacies are seeing improved survey results as they go through the accreditation process multiple times. Each cycle allows for a deeper dive for the ACHC Surveyor and a recalibration opportunity for the pharmacy. Generally speaking, we find that providers who embrace the concept of accreditation continually improve over time.

Having been a provider that took my own practice through accreditation, I completely understand the challenges that pharmacies face on any given day. Very often, the items that are missed do not indicate a blatant disregard of the standard, but a missing component of compliance that was either misunderstood or not satisfied because the pharmacy put it off to deal with day-to-day issues encountered in patient care. For example, most pharmacies have the structure for a suitable training program and competency assessment for staff, but sometimes they don't complete them

as frequently as required because other priorities are more pressing on a given day. Although this may be inadvertent, it can nonetheless result in deficiency citations.

It is important to note that pharmacy standards in our programs that touch compounding will be updated when revisions of USP <795> and <797> are finalized. I expect there will be new deficiencies as pharmacies move toward compliance with the new requirements. This should not be interpreted as a negative. Delivering an educational accreditation experience, including the survey, provides the pharmacy with a roadmap to close its gaps. This is one of the added values that comes from partnering with ACHC for accreditation.

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The ACHC pharmacy team continues to look for ways to use customer feedback to improve our process, specifically with training and consistency among surveyors and standards interpretation. In the coming year, we plan to build on the momentum that the pharmacy program has created by improving internal performance and building increased value in the programs that we offer. I speak for the entire team when I say that your feedback is welcomed and valued.



Jon Pritchett, PharmD, RPh, BCSCP
Program Director



PHARMACY SERVICES AND DISTINCTIONS

Services

Ambulatory Infusion Center
Community Retail Pharmacy
Infusion Nursing

Infusion Pharmacy
Long-Term Care Pharmacy
Mail Order Pharmacy
Specialty Pharmacy

Specialty Pharmacy without DMEPOS
PCAB Non-Sterile Compounding
PCAB Sterile Compounding

Distinctions

Telehealth Hazardous Drug Handling

Infectious Disease Specific to HIV
Nutrition Support

Oncology
Rare Diseases and Orphan Drugs

WHAT IS PCAB?

State Boards of Pharmacy are responsible for the pharmaceuticals delivered to patients in their state. To meet this responsibility, they license and regulate compounding pharmacies. In 2007, national standards were created when eight of the nation's leading pharmacy organizations established the Pharmacy Compounding Accreditation Board (PCAB®) to validate the quality and consistency of compounded medications.

PCAB Standards are widely recognized as the benchmark for excellence. They are based on U.S. Pharmacopeia Convention (USP) guidelines and separated into distinct requirements for sterile and non-sterile preparations.

In 2014, PCAB became a brand of Accreditation Commission for Health Care, Inc. and has continued to lead in providing education and quality evaluation nationwide.

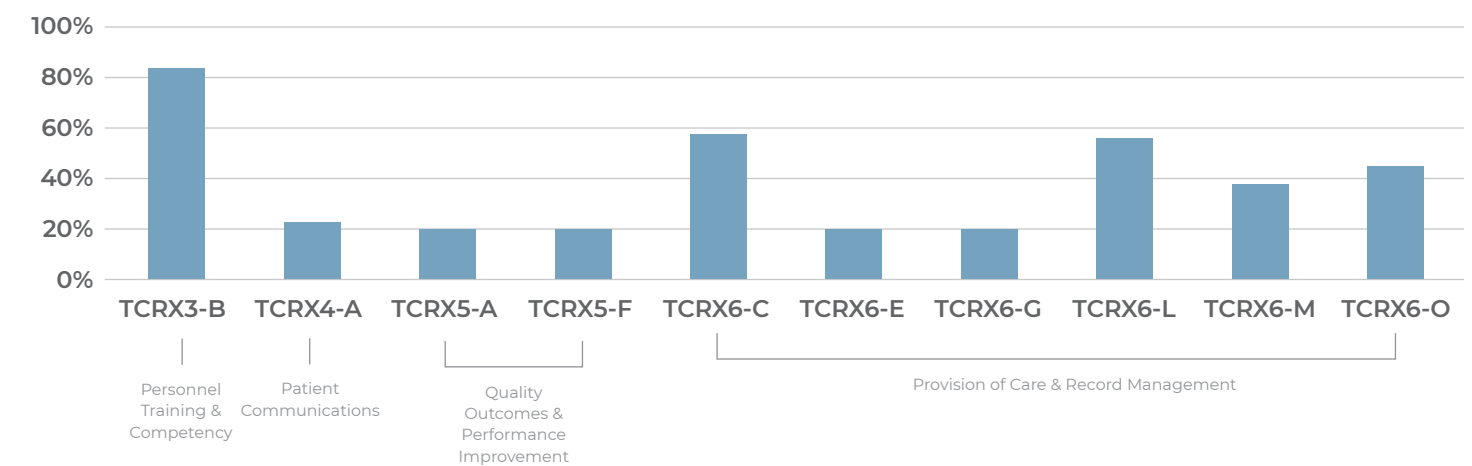


PCAB DATA INSIGHTS

Five of the ten most frequent deficiencies for this period were cited on 20% or fewer of the surveys performed. Of greater concern are the top three standards that were cited on more than half of these surveys.

- **TCRX3-B** relates to training and education, e.g., gloved fingertip sample and competency assessment for recurring, monthly duties, competency assessment for those providing process oversight). (See page 8 for additional detail.)
- **TCRX6-C** relates to appropriate storage practices, e.g., maintenance of appropriate temperature, humidity and other environmental conditions to ensure integrity and security of components. (See pages 9-10 for additional detail.)
- **TCRX6-L** relates to USP guidelines on infection control and risk management, e.g., personnel movement from “dirty” to “clean” areas, garbing and performing aseptic processes. (See pages 11-12 for additional detail.)

COMPOUNDING PHARMACY DEFICIENCIES (PCAB PROGRAM)



COMPOUNDING PHARMACY



PERSONNEL TRAINING AND COMPETENCY

TCRX3-B

Overview of the requirement

Policies and procedures must be developed and applied for sterile compounding personnel to receive training and education.

Comment on deficiencies

Deficiencies are cited when policies and procedures were not implemented and followed for training and education of sterile compounding personnel.

Frequency of citation: 85%

Examples of Surveyor findings

- Sterile compounding personnel did not have an annual post media-fill gloved fingertip sample and/or organizations were missing documentation of the initial gloved fingertip testing results.
- Organizations lacked a documented competency assessment for monthly duties.

Tips for compliance

- Review the policies and procedures for personnel training.
- Re-educate staff on competency requirements.
- Assign responsibility to the HR manager to ensure that all personnel complete the required training and education prior to receiving independent work assignment.

PATIENT COMMUNICATIONS

TCRX4-A

Overview of the requirement

The standard ensures that a record is maintained for each patient and that the record contains complete, accurate clinical information.

Comment on deficiencies

The standard was cited when patient records were missing relevant and required elements.

Frequency of citation: 23%

Examples of Surveyor findings

- Based on review of policies and procedures, patient records were missing documentation showing that the medication profile was reviewed.
- Patient records did not identify patient drug allergies or other diseases/conditions.

Tips for compliance

- Assign responsibility to the Pharmacy Director to ensure that all required elements of the record and assessments are completed and documented appropriately.

QUALITY OUTCOMES & PERFORMANCE IMPROVEMENT

TCRX5-A

TCRX5-F

Overview of the requirement

The organization must implement a comprehensive program for performance improvement (PI) activities.

Comment on deficiencies

Deficiencies resulted from incomplete PI programs.

Frequency of citation: TCRX5-A: 21% | TCRX5-F: 21%

Examples of Surveyor findings

- PI programs did not include data collection from patient records or communicable diseases trends.
- Quarterly reports are not prepared.
- Infection risk has not been included as a PI assessment activity.
- Annual reports were not created reviewing the PI program and activities.

Tips for compliance

- Review the current PI program and ensure that all required elements are included.
- Re-educate those responsible for coordinating PI activities to document and include all required information in the PI report.

PROVISION OF CARE & RECORD MANAGEMENT

TCRX6-C

Overview of the requirement

Policies and procedures support appropriate storage practices for pharmaceutical components and preparations.

Comment on deficiencies

The standard was cited when pharmacy staff did not follow policies for storage of pharmaceutical components and preparations.

Frequency of citation: 58%

Examples of Surveyor findings

The following was observed as deficient practice:

- Unlabeled capsules.
- Recorded temperatures for a cooler were not within the defined acceptable range and no corrective action was taken.
- No documentation existed of humidity/temperature monitoring in medication storage areas.
- Inconsistent documentation of the disinfection agent used.
- Cleaning of pharmacy areas not documented.

Tips for compliance

- Routinely inspect storage areas for compliance with manufacturer or USP requirements.
- Maintain temperature and humidity logs and a defined process for managing “out-of-range” readings.

TCRX6-E

Overview of the requirement

Shipping procedures must ensure that pharmaceuticals are maintained under appropriate conditions.

Comment on deficiencies

Deficiencies resulted from inappropriate conditions of the shipping materials.

Frequency of citation: 20%

Examples of Surveyor findings

- Not all shipping containers or methods were tested.
- Coolers/boxes did not reflect consistent packaging.
- Temperature controls using ice bricks for the shipping boxes were at staff discretion, rather than using a defined pack-out schematic.

Tips for compliance

- Review the policies and procedures with staff on proper storage and shipping methods.
- Conduct a review of all shipping materials and ensure that they meet the requirements.

TCRX6-G

Overview of the requirement

Organizations must implement the updated Master Formulation Record (MFR) for each non-sterile and high risk sterile compounded preparation.

Comment on deficiencies

Deficiencies resulted when organizations used older (not current) processes or failed to include the required elements in the MFRs.

Frequency of citation: 21%

Examples of Surveyor findings

- The MFR mixing instructions in use for sterile hazardous compounding reflect an older process in which powders were weighed and mixed in the ISO 8 positive pressure room instead of the new configuration and process where the weighing of the powders is performed inside of the ISO 7 negative pressure room.
- MFRs did not include a description of the desired final product, BUD source, or identity of equipment used (e.g., EMPs and scales).
- The formula for Amlodipine capsules did not include a salt form calculation.

Tips for compliance

- Review the MFR policies with the pharmacy staff and educate for best practices in compounded preparations and documentation.
- Develop a process for tracking changes to the MFR and making relevant updates, including education and training.

TCRX6-L

TCRX6-M

TCRX6-O

Overview of the requirement

TCRX6-L, TCRX6-M

- Policies and procedures within the pharmacy must be in accordance with the United States Pharmacopeia (USP) standards.

TCRX6-O

- Pharmacies must ensure that policies are implemented to monitor controlled air environments.

Comment on deficiencies

TCRX6-L, TCRX6-M

- Deficiencies resulted from pharmacies not following USP standards related to infection control and risk management.

TCRX6-O

- Deficiencies resulted from improper maintenance of the air environment.

Frequency of citation: TCRX6-L: 55% | TCRX6-M: 38% | TCRX6-O: 47%

Examples of Surveyor findings

TCRX6-L, TCRX6-M

- Based on observation of hand washing, gowning, and gloving, staff crossed the line of demarcation into the “dirty” side after donning booties and placing one of these booties back on “clean side.”

COMPOUNDING PHARMACY

- Sterile technician moved back and forth from ante room to buffer room without reapplying surgical scrub/gloves.
- Supplies were not cleaned as they were transferred from uncontrolled to controlled areas.
- Staff observed removing hands from ISO Class 5 environment to retrieve supplies from a cart without sanitizing with sterile 70% isopropyl alcohol.

TCRX6-O

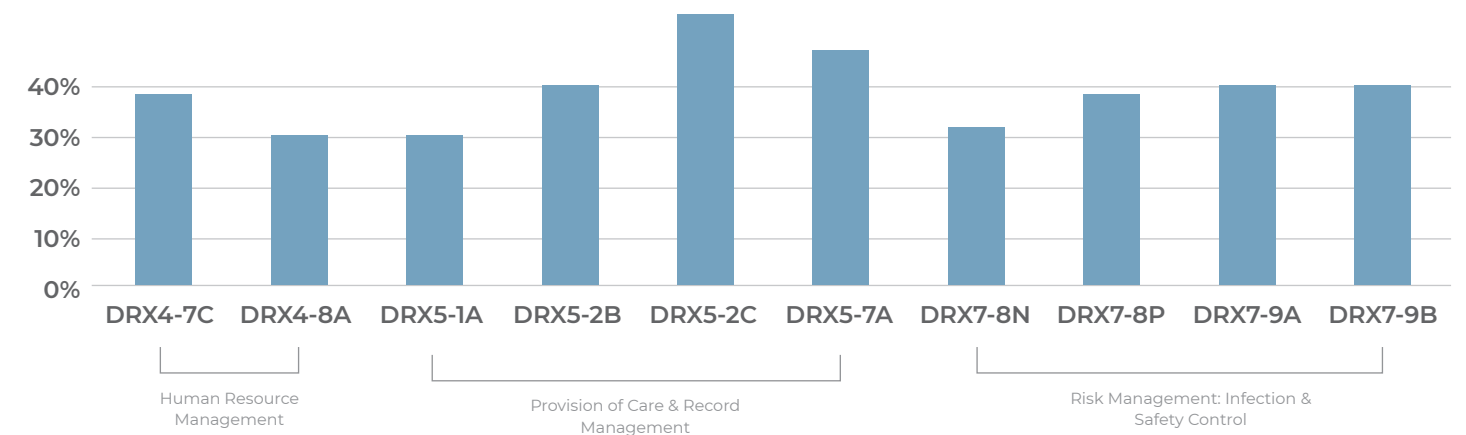
- Smoke test not documented on clean room certification.
- During floor cleaning in the buffer room, cart was not rolled, wheels cleaned and then rolled back to ensure that area under the cart and wheels was clean.
- Daily, weekly, monthly cleaning logs did not include the agents used and the dwell time.

Tips for compliance

- Review the policies and procedures with all personnel on sterilization and infection control.
- Conduct frequent observational audits of the pharmacy to monitor risk management protocol.



AMBULATORY INFUSION CENTER, COMMUNITY RETAIL, INFUSION, MAIL ORDER, AND SPECIALTY PHARMACY DEFICIENCIES



HUMAN RESOURCE MANAGEMENT

DRX4-7C

Overview of the requirement

Policies and procedures must be developed and applied for sterile compounding personnel to receive training and education prior to independent work assignment.

Comment on deficiencies

Deficiencies were cited when organizations developed policies and procedures without all the required elements.

Frequency of citation: 29%

Examples of Surveyor findings

Document review revealed the following missing documentation:

- Staff did not have an annual competency assessment for cleaning and disinfecting procedures.
- No current observational audit for cleaning and disinfecting procedures.
- Files reviewed did not contain documentation pertaining to equipment competency.

Tips for compliance

- Review the policies and procedures for personnel training.
- Re-educate staff on competency requirements.
- Assign responsibility to the HR Manager to ensure that all personnel receive the required training and education.

DRX4-8A

Overview of the requirement

Organizations must develop and implement an education plan as part of in-service training for each classification of personnel.

Comment on deficiencies

The standard was cited when a plan for on-going education was not implemented appropriately.

Frequency of citation: 18%

Examples of Surveyor findings

- Ongoing education plans did not include all required elements (including, but not limited to, Grievances/Complaints, Infection Control Training; Cultural Diversity; Client/Patient Rights and Responsibilities).
- Documentation did not show that annual in-service/education was completed within 12 months.

Tips for compliance

- Assign responsibility to the HR Manager to ensure that all personnel receive annual in-service training, and that the education is documented.

PROVISION OF CARE AND RECORD MANAGEMENT

DRX5-1A

Overview of the requirement

The standard ensures that a record is maintained for each patient and that the record contains accurate clinical information.

Comment on deficiencies

The standard was cited when patient records were missing relevant and required elements.

Frequency of citation: 17%

Examples of Surveyor findings

- Upon review of policies, procedures and patient records, the patient records were missing initial and ongoing assessments, physician orders for all medications, and emergency contacts.

Tips for compliance

- Assign responsibility to the Pharmacy Director to ensure that assessments and all other required elements of the record are completed and documented appropriately.

DRX5-2B

Overview of the requirement

All patients must be evaluated and assessed for their needs before receiving pharmacy services.

Comment on deficiencies

Deficiencies resulted from incomplete assessments or failure to evaluate patients before initiating services.

Frequency of citation: 17%

Examples of Surveyor findings

- Initial assessments did not include all required elements including functional limitations, cognitive assessments, mental status evaluation.
- Charts did not have evidence of an initial assessment being conducted.
- Records revealed that initial assessments were completed after services were initiated.

Tips for compliance

- Assign responsibility to the Pharmacy Director to review assessments for timely completion and accuracy.
- Conduct quarterly reviews of initial assessments to ensure completion.

 **DRX5-2C****Overview of the requirement**

The standard ensures that each client/patient receives an individualized, written plan of care.

Comment on deficiencies

The standard was cited when plans of care were not entered, were incorrect, or were incomplete.

Frequency of citation: 30%

Examples of Surveyor findings

- Care plans do not address specific outcome goals, monitoring and evaluating progress towards these goals, or identification of any functional limitations that impact the care.
- Pharmacist did not establish goals for vancomycin trough levels.
- No documentation of the patient's problems/needs or expected outcomes/goals.
- Missing start of care date.
- Missing initial plan of care which should include therapy goals, problems, intervention, and monitoring.

Tips for compliance

- Ensure all patients have an individualized plan of care that documents the issues identified in the initial assessment.
- Assign responsibility to the Pharmacy Director to review plans of care for accuracy and completion.
- Conduct routine audits of patient plans of care to ensure accuracy and completion.

 **DRX5-7A****Overview of the requirement**

A registered pharmacist must review and document all medications.

Comment on deficiencies

The standard was cited when medication profiles are incomplete.

Frequency of citation: 17%

Examples of Surveyor findings

- Patient records revealed incomplete medication profiles.
- Charts did not document that the medication profile was reviewed by a registered pharmacist prior to dispensing/administration.
- Records did not include height/weight and other relevant details needed to verify correct dosage.

Tips for compliance

- Ensure that medication profiles are complete and accurate, as per physician's orders.
- Review the policies and procedures related to reviewing medication profiles and documentation.

RISK MANAGEMENT: INFECTION AND SAFETY CONTROL **DRX7-8N** **DRX7-8P****Overview of the requirement**

DRX7-8N

- Policies and procedures within the pharmacy must be in accordance with the United States Pharmacopeia (USP) standards.

DRX7-8P

- Pharmacies must ensure that policies are implemented to maintain a quality air environment.

Comment on deficiencies

DRX7-8N

- Deficiencies resulted from pharmacies not following USP standards related to infection control and risk management.

DRX7-8P

- Deficiencies resulted from inadequate cleaning and disinfecting measures.

Frequency of citation: DRX7-8N: 27% | DRX7-8P: 19%

Examples of Surveyor findings

DRX7-8N

- Upon observation of hand washing, gowning, and gloving, staff crossed the line of demarcation back into the "dirty" side after donning booties and placing one of these booties back on "clean side."
- Supplies were not cleaned as they were transferred from uncontrolled to controlled areas.
- Sterile technician moved back and forth from ante room to buffer room without reapplying surgical scrub/gloves.
- Staff observed removing hands from ISO Class 5 environment to retrieve supplies from a cart without sanitizing with sterile 70% isopropyl alcohol.

DRX7-8P

- Smoke test not documented on clean room certification.
- During floor cleaning in the buffer room, cart was not rolled, wheels cleaned and then rolled back, to ensure that area under the cart and wheels were clean.
- Daily, weekly, monthly cleaning logs did not include the agents used and the dwell time.

Tips for compliance

- Assign responsibility to the Pharmacy Director to ensure that all required elements of the record and assessments are completed and documented appropriately.

 **DRX7-9A**
Overview of the requirement

Facilities must establish policies related to purchasing and safely storing pharmaceuticals.

Comment on deficiencies

Deficiencies resulted from incomplete documentation and infrequent monitoring of the pharmaceutical storage area.

Frequency of citation: 20%

Examples of Surveyor findings

- Storage area for pharmaceuticals did not have daily humidity monitoring records.
- Temperature logs indicate out of range temperatures for the refrigerator, but no corrective action was taken.
- No designated quarantine area for unusable drugs.
- Monitoring and cleaning activities for the sterile compounding suite not documented.

Tips for compliance

- Review the best practices and policies related to documentation of pharmaceutical storage, and the necessary monitoring and cleaning procedures.

 **DRX7-9B**
Overview of the requirement

Shipping procedures must ensure that pharmaceuticals are maintained under appropriate conditions when shipped.

Comment on deficiencies

Deficiencies resulted from inappropriate conditions of the shipping materials.

Frequency of citation: 23%

Examples of Surveyor findings

- Not all shipping containers or methods were tested.
- Coolers/boxes were not consistently packaged for shipping.
- Temperature controls using ice bricks for the shipping boxes were used per staff discretion, rather than as part of a defined pack out schematic.

Tips for compliance

- Review the policies and procedures with staff on proper storage and shipping methods.
- Conduct a review of all shipping materials and ensure that they meet the requirements.

**We're here to help.**

To learn more, visit our website at [achc.org](https://www.achc.org), call us at (855) 937-2242, or email customerservice@achc.org.

ACHC OFFERS MORE, SO YOU CAN OFFER MORE TO YOUR PATIENTS



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BY PROVIDERS.

139 Weston Oaks Ct.
Cary, NC 27513

achc.org

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