

Understanding URAC Accreditation and Medication Distribution

Six Questions for Specialty Pharmacy Teams



Every medication shipment connects pharmacy operations with patient care. Understanding how temperature control, packaging performance and daily procedures work together can help your team protect medication integrity and prepare for accreditation review.

1 What role do URAC and ACHC play in pharmacy operations and packaging?



URAC and the Accreditation Commission for Health Care (ACHC) offer pharmacy accreditation programs that support quality, patient safety and continuous improvement.

URAC's Specialty Pharmacy Accreditation v6.0 addresses pharmacy operations, patient care and medication distribution - including qualification testing, packing and shipping procedures, and performance reviews. ACHC offers accreditation tailored to pharmacy services, including specialty, mail order and infusion, with requirements relevant to each pharmacy's scope of care.

For pharmacies shipping medications, packaging is one part of a broader responsibility to protect medication integrity and support reliable delivery. Your team should assess packaging and shipping practices against the specific requirements of its accreditation program.

2 Why medications require temperature management during delivery?



Temperature management isn't limited to refrigerated medicines.

URAC's expectations address medication storage and delivery across temperature ranges, including room temperature medications.

Use each medication's labeled temperature requirements - the label claim - as the basis for selecting and testing your shipping solution. Manufacturer excursion data should support the assessment of unexpected temperature exposures, rather than serve as the target for routine shipping.

Consider the full journey, including seasonal weather, transit time and possible delays, when determining the protection your medications need.

3 What role does thermal packaging play in accreditation readiness?



Thermal packaging supported by relevant testing helps your pharmacy demonstrate how it protects medications when they are dispatched. In selecting thermal packaging, you should review test data provided by your vendor to determine its suitability for the products you ship, the external temperatures it will encounter and the shipping duration.

Testing should use actual or representative product loads that reflect what and how you actually ship. Ensure the tests you undertake reflect typical product quantities and the way in which the way the shipper is packed. Your packaging partner should be able to provide you with pack out instructions to make sure the shipper consistently performs in line with your expectations.

4 What documentation can help support accreditation readiness?



URAC's public standards overview identifies qualification testing and documented packing and shipping procedures as distribution topics. A practical preparation file can bring together the evidence and instructions your team uses, including:

- ✓ Medication distribution criteria and the information supporting them
- ✓ Packaging qualification reports and their applicable conditions
- ✓ Current pack-out and shipping procedures
- ✓ Staff training records and documentation of procedural changes

Organize these materials so your team can connect the evidence to the packaging configurations and procedures used in daily operations.

5 How should pharmacies prepare for shipping and delivery issues?



URAC's distribution framework includes holding and tracking shipments, and handling delivery breakdowns. Clear responsibilities help teams respond when a shipment is delayed, damaged or potentially exposed to unsuitable conditions. [2]

A practical response process should identify who reviews the event, how medication-specific information informs the assessment, how the decision is documented and how the patient receives timely guidance. Include steps for coordinating replacement or other follow-up when appropriate.

6 How can teams maintain a consistent distribution process over time?



URAC includes distribution auditing and accuracy monitoring in its framework. [2] Use ongoing review to understand whether daily practice remains consistent with your documented approach.

Review activities can include observing pack-outs, examining delivery exceptions and complaints, and checking whether corrective actions resolved recurring issues. Include annual performance qualification (PQ) testing in your quality plan to assess packaging under actual shipping conditions, using representative product loads and the medications' labeled temperature requirements.

When packaging materials, product loads, delivery services or procedures change, assess whether additional testing is needed and update instructions and training accordingly.

New to Temperature Controlled Shipping?

Not sure where to start? Don't worry - we've been partnering with the Life Sciences and Healthcare industries for decades and we'll be happy to guide you through what you need to consider.

Here's what you need to know to ensure you have the right solution to protect your product and the patient.



Temperature

At what temperature does your product need to be maintained on its journey from dispatch to reaching the patient to ensure its integrity is safeguarded?



Transit Time

How long does the shipper need to be able to maintain the desired temperature? This will be determined by your choice of transportation partner and service level.



Payload

These are the physical characteristics of the product you are shipping. Measure the dimensions so you can determine the size of the shipper you need.



External temperature

What external temperatures are likely to be experienced during the shipment of your product and the season of the year it's being transported? This is often referred to as the profile.

On top of these considerations, you are likely to have others too, like the cost of the shipper relative to the product cost or sustainability pressures. We can help find the optimal solution for your particular set of needs.

Whether your pharmacy is already URAC Accredited or just beginning the journey, ThermoSafe provides thermal packaging solutions and the expert guidance of our thermal engineers you need to design a distribution process that guarantees the stability of critical patient medications, safeguarding patient health.

ThermoSafe is your trusted partner for temperature assurance packaging.

Contact us | thermosafe.com

Dive Deeper

This overview is educational and is not a complete statement of URAC requirements. Consult the full standards and guidance applicable to your organization's accreditation cycle.

1. URAC — Specialty Pharmacy Accreditation program overview



2. URAC — Specialty Pharmacy Accreditation v6.0 Standards at a Glance



3. URAC — How Pharmacy Accreditation Programs Help Address Temperature Management



4. USP — General Chapter 1079 on storage and transportation risk management



5. Thermal Packaging's Role in URAC Accreditation

