

ASHP Executive Forum on
COLD CHAIN MANAGEMENT

Resource Guide #2

**HEALTH-SYSTEMS DESIGN
TO OPTIMIZE COLD CHAIN
MANAGEMENT**

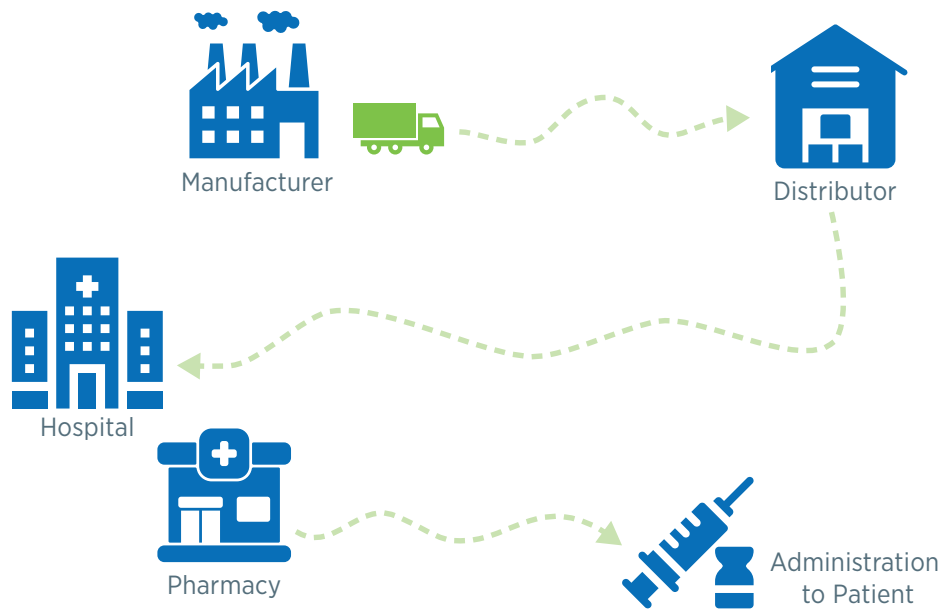


BACKGROUND

Pharmacists play a critical role in product procurement, storage, handling, and transport of medications for hospitals, health systems, and alternate sites of care within their communities. The rapid introduction of medicines requiring precise temperature control, including biologics, compounded infusions, and specialty drugs, will likely expand requirements for unique handling, storage, and transportation needs. Leveraging the expertise of pharmacy leaders in advancing cold chain management and collaboration with all supply chain stakeholders is needed to optimize design and innovation of cold chain processes and supporting technologies. The importance of cold chain expertise

and capacity was amplified by the development of COVID-19 vaccines that required a reliable cold-chain — from the point of manufacture to the point of administration — at massive scale. Pharmacists will continue to provide leadership and build upon their expertise in the management of the drug supply chain and its integrity. This initiative is part of the ASHP Innovation Center’s mission to influence innovation, collaboration, transparency, and digital transformation in the safe and effective use of medicines.

Diagram of Cold Chain Stakeholders



INTRODUCTION: HEALTH-SYSTEMS DESIGN TO OPTIMIZE COLD CHAIN MANAGEMENT

This is the second of three resource guides developed through a series of ASHP executive forums. The first resource guide, Pharmaceutical Cold Chain Management in Health Systems, addressed the current state of cold chain management, supportive infrastructure needed for optimal cold chain management, strategic priorities across stakeholders, and pharmacy operations and design considerations.¹ Eighteen pharmacy leaders convened on October 11, 2022, for the second executive forum, which included experts representing pharmaceutical manufacturers and distributors, regulatory and accreditation agencies, shipping partners, group purchasing organizations, and technology solutions. The objectives of the forum were to:

1. Describe health-system design for cold chain management.
2. Discuss barriers and identify infrastructure needs for optimal cold chain management.
3. Identify knowledge gaps related to regulatory compliance and considerations for health systems.
4. Develop elements of a self-assessment tool for health systems, industry, manufacturers, distributors, and cold chain suppliers.

Session participants engaged in a guided discussion focused on health-systems design to optimize cold chain management, including challenges, lessons learned, strategic priorities, and self-assessment guidance. The third and final forum will explore the future of cold chain management in the health industry, including new technologies and building collaboration across stakeholders.

COMMONLY USED TERMS

Cold Chain Monitor (CCM) is, generally, a single-use device that monitors the temperature inside a vaccine shipping container. CCMs should be thrown away after being checked. CCMs are stored in a separate compartment of the shipping container.²

Hub-and-Spoke Model is a supply chain distribution model where product is shipped to a regional location (hub) for subsequent distribution to local sites (spokes).

Mean Kinetic Temperature (MKT) is the single calculated temperature at which the total amount of degradation over a particular period is equal to the sum of the individual degradations that would occur at various temperatures. MKT may be considered as an isothermal storage temperature that simulates the non-isothermal effects of storage temperature variation. It is not a simple arithmetic mean.³

Temperature Excursion is any temperature reading that is outside the recommended range for vaccine storage as defined in the manufacturer's package insert.²

COLD CHAIN COMPLIANCE WITH STANDARDS AND REGULATIONS

A solid foundation for ensuring cold chain integrity begins with regulatory and compliance requirements related to temperature control, including current and pending temperature control standards. The U.S. Pharmacopeia (USP) first mandated temperature control standards in 1995 as best practice guidance to ensure the integrity of drug products from the point of manufacture to the patient. The relevant chapters affecting cold chain compliance and general temperature control include USP Chapter <659> Packaging and Storage Requirements and USP <1079> Risks and Mitigation Strategies for the Storage and Transportation of Finished Drug Products.^{4,5} Chapter <1079> has several subchapters addressing specific elements for compliance, and this guidance continues to evolve (See Table 1). Understanding risk and mitigation strategies provides a framework for a proactive approach to excursion control and quality management.



Understanding risk and mitigation strategies is the key to moving from temperature excursion panic to temperature excursion management.

USP LIAISON

Risk identification is the first step in minimizing potential causes of possible harmful temperature variations, or excursions. Information used to identify risk can include tracking data, failure mode and effects analysis, experience, and product and process requirements. Risk points occur across the supply chain continuum and include procurement and sales, receiving and shipping, storage, and picking of drug products. Mitigation strategies, or risk reduction actions, can control or minimize risk. Processes or technologies that improve the timely detection of potential risks are an example of a risk control strategy. Mitigation strategies may also include process integrity documentation (e.g.,

manuals, procedures, protocols, and records), training, resources, qualification and validation. See Table 2 for examples of risk and mitigation strategies. Forum participants acknowledged the downstream effects of noncompliance, underscoring the negative impact on patient outcomes and risk to the institution (e.g., financial, regulatory, and reputation). Risk and mitigation review should also be part of an overall quality management system (QMS) for excursion management (See Figure 1). The QMS should include a process for proactively considering potential risks and their mitigation as well as retrospective risk review of individual deviations and trends. There should also be a process for timely identification of and response to controlled room temperature (CRT) and controlled cold temperature (CCT) excursions. There can be short-term and long-term excursions at any point during transportation or storage, throughout the supply chain, up to the point of administration to the patient. Each excursion should be documented and handled with an appropriate deviation or risk assessment.

Figure 1: Elements of a Drug Product Storage and Handling Quality Management System



Product disposition should be established on the basis of a thorough assessment of the excursion.

Key elements required to make a decision about product disposition include:

- Temperature (may be variable over time)
- Duration of excursion (24 hours or less)
- MKT (inside or outside of acceptable limit)

Unplanned excursions usually fluctuate in temperature over time as opposed to a static temperature change. If the temperature at which the excursion occurred was static over time, it would be easier to evaluate the impact on product stability. MKT is a way to summarize the time history of a product’s temperature exposure with a single effective or virtual temperature. USP <659> provides guidance on temperature excursion allowance and MKT limits.⁵ A summary of the guidance and resources for calculating MKT is provided in Appendix A.

Having a good understanding of best practices for excursion management, including identification of excursions, risks, and mitigation, is fundamental to optimizing cold chain design and management.

Table 1: Current and Pending USP Chapters that Address Storage, Distribution, and Excursions

<p>General</p> <p><659> Packaging and Storage Requirements</p> <p>Storage and Transportation</p> <p><1079> Risks and Mitigation Strategies for the Storage and Transportation of Finished Drug Products</p> <p><1079.1> Storage and Transportation of Investigational Drug Products</p> <p>Temperature Control</p> <p><1079.2 > Mean Kinetic Temperature in the Evaluation of Temperature Excursions During Storage and Transportation of Drug Products</p> <p><1079.3> Monitoring Devices – Time, Temperature, and Humidity</p> <p>< 1079.4> Temperature Mapping for the Qualification of Storage Areas</p> <p><1079.5> Qualification of Shipping Systems</p> <p><1079.6> Transport Route Profiling Qualification</p> <p><1079.7> Information Systems</p>

Table 2: Storage and Transport Main Risks and Mitigation Strategies

Risk Category	Example	Mitigation Strategy	Mitigation Type
Procurement and Sales	Product sourced from unlicensed supplier	Quality agreement between wholesaler and suppliers	Documentation
Receiving and Shipping	Mishandling of drug along the supply chain-affects product integrity	Ensure appropriate policies and procedures are in place, appropriate staff training, and sufficient staffing	Training and Resources
Shipping	Shipped product arrives at destination with critical cold storage temperature excursion	Shipping packaging qualification	Qualifications/Validation
Storage	Critical cold storage temperature excursion in remote storage location	Install remote monitoring devices including alarms and calibrate regularly	Resources

Table adapted from USP chapter <1079>

KEY TAKEAWAYS

- Understanding risks and mitigation strategies is the key to moving from temperature excursion panic to temperature excursion management.
- When evaluating temperature excursion allowances for CCT and CRT, duration of excursion and MKT (inside or outside of limit) need to be considered.
- There was consensus that the most important risk associated with excursions is the impact on clinical care, and ultimately, ensuring optimal patient outcomes. Other risks include financial risk to the institution, including significant waste of drug product.
- Monitoring for and identifying temperature excursions needs to be multimodal and may vary depending on the movement of the product (external temperatures, distance of travel, etc.).
- Ongoing assessment and a QMS are needed to ensure compliance.

COLD CHAIN EXCURSION MANAGEMENT

The elements of cold chain excursion management include establishing: policies and procedures; ways to quickly identify excursions, preferably with real-time monitoring; a process for mitigating excursion risk; and a process for excursion investigation and reporting. There should also be a training program and competency assessment for all affected personnel (i.e., those responsible for receiving, storage, and transport of medications), both internal and external to the pharmacy (See Figure 2). There should be a collaborative approach within the organization and with manufacturers, distributors, technology vendors, and shipping partners. Policies and procedures should be readily accessible and should outline responsibilities for investigating possible excursions, taking into account seasonal and regional variations in temperature.

There are several ways to identify excursions. Participants noted that some excursions are patient-

or staff-reported at the point of receipt, but many occur via automated alert systems. Technology solutions for tracking excursions during transport include smart tags that change color when the temperature exceeds 8 °C, electronic monitors, and infrared scanners. Excursion mitigation may include determining product integrity and potential loss, evaluating reference data, contacting the manufacturer or supplier, developing a mitigation plan, and notifying affected areas or patients. Excursion investigation and reporting should include an action plan for loss recovery and mitigation efforts. Several participants described their reporting processes; most report specialty drug loss because it is required for accreditation. Others bill ancillary areas for drug loss or track losses as part of a quality management program.

Figure 2: Elements of Excursion Management



POLICIES AND PROCEDURES ESTABLISHED

- Staff is trained
- Policies and procedures are readily accessible
- An individual is tasked with oversight
- Address seasonal and regional temperature differences



EXCURSION IDENTIFICATION

- Within organization
 - » internal to pharmacy
 - » external to pharmacy
- External to organization
 - » manufacturers
 - » wholesalers
 - » shipper



EXCURSION MITIGATION

- Evaluate product integrity
 - » Contact manufacturer
 - » Reference data
- Develop mitigation plan
- Notification to impacted areas/people



EXCURSION INVESTIGATION AND REPORTING

- Track and trend excursions
- Conduct root cause analysis
- Quantify and report loss (if applicable)
- Financial recovery if possible

Challenges with managing cold chain excursions include:

- Senior leaders need to be educated about risk, mitigation strategies, and required resources (e.g., equipment, technology, and space).
- It is difficult to track additional (cumulative) excursions across settings, end-to-end.
- It can be time-consuming to investigate and mitigate excursions when multiple line items are involved.
- What occurs (e.g., process for monitoring and identifying excursions) once a product is at the end-user location, such as clinic sites or in the patient's home, is often uncertain.
- Lack of information can affect the ability to answer patients' questions about excursions that occur in the home.
- Use of technology requires validation of user competency and product reliability.

One way to address challenges is to work with suppliers, wholesalers, and shippers to take advantage of the technology they are currently using and better integrate it into health-system monitoring processes. For example, some manufacturers use advanced technology solutions such as internal data loggers together with validated shipping containers and thermal monitoring. Calibrated modeling and advanced data analytics can predict and identify excursions based on the system's excursion history. These technologies increase transparency and confidence of product integrity throughout transport.

PRACTICAL CONSIDERATIONS FOR FACILITY DESIGN AND EQUIPMENT STRATEGIES

Although there is limited information about product loss or effects on patient care, inadequate cold storage is estimated to result in the loss of at least \$10 million worth of vaccines annually.⁶ While vaccines are closely tracked and reported, good information is lacking for other drug product losses. Pharmacists are uniquely positioned to lead their organizations in preparing for disruptive events, educating leadership, preventing product losses, and thus, minimizing risk to the organization and patients. Ideally, organizations should strive to provide the same level of care before, during, and after a product loss.⁷ A collaborative approach is needed within the organization and when working with external stakeholders. Managing temperature control during natural disasters has been a learning opportunity for hospitals and health systems; losses will be much greater at sites that are not prepared. Depending on the size and geographical distribution of the organization, significant time may be needed to develop mitigation strategies and processes; this requires strong organizational support. One approach to ensure consistency across the system



When we evaluated losses across the system after widespread hurricane damage, the sites that were prepared fared much better than sites that were not.

HEALTH-SYSTEM PHARMACY LEADER

is the implementation of a hub-and-spoke model. For example, health systems may create a hub for each region and invest in infrastructure and redundancy, considering the physical plant, drug inventory locations, and maintain capacity to store offsite product, should it need to be brought to the central location. Adequate storage units and facility controls to account for this redundancy and backup are needed and may require a significant capital investment. Finally, it is recommended that organizations conduct a quarterly review of all drug inventory stored in ancillary locations to minimize the inventory amount stored in a single location or unit.

Key recommendations for excursion management and systems design to mitigate hazards and loss include:

- Increase redundancy and reduce variation in the system based on risk of loss (e.g., high value locations [high-cost drugs and high-cost inventory]). This has implications for the amount of storage and space needed (including redundant locations), additional monitoring devices, and backup power sources.
- Find ways to collaborate with external stakeholders (e.g., shippers, wholesalers) to review reasons for excursions and identify process improvement opportunities. For example, include shippers and wholesalers when conducting root cause analyses on excursions, when applicable.
- Work with USP to clarify interpretation of standards, including development of toolkits to assist with compliance (similar to what was done for vaccines).
- Strive for centralized monitoring and management of temperature excursions.

- Where possible, centralize receiving and product distribution to minimize variation within the system (e.g. hub-and-spoke model).
- Consider additional mitigation efforts for ancillary areas:
 - » Improve accountability at remote sites (e.g., offices and clinics) to increase awareness and management of product storage and integrity (e.g., cost-transfer losses).
 - » Put loggers in the shipping totes to monitor delays from time to receipt to transport to clinics.
 - » To minimize inventory in each remote location, evaluate products stocked and dollar amount annually.

BRINGING IT ALL TOGETHER: COLD CHAIN SELF-ASSESSMENT TOOL

Throughout the first two cold chain forums, it became apparent that preparedness is critical to maintaining drug product integrity, reducing loss, and ensuring the highest quality patient outcomes. Collaboration across settings and within health systems is critical, and every person responsible for drug receipt, storage, or transport must play their part. Based on input from cold chain leadership and participants at this forum, a **Cold Chain Self-Assessment Tool** was created to support health-system pharmacists develop their cold chain management strategies as seen in Appendix B. Core domains of the tool include:

- **Policies and Procedures** — Policies and procedures define oversight and responsibility for drug integrity, appropriate temperature control, monitoring, and investigation and reporting in all areas where drugs are stored.
- **Education and Training** — All staff with access to medications are trained in policies and procedures for appropriate storage of medications, including actions to take after a known or suspected temperature excursion.
- **Receipt and Storage** — Receiving checks (e.g., temperature loggers, packaging, and heat sensors) and storage requirements (monitoring

and capacity) are established to maintain product integrity.

- **Shipping and Transport** — Monitoring and mitigation strategies (e.g., packaging validation) ensure temperature is maintained throughout shipping and transport, either to the patient or to other locations within the health system.
- **Monitoring** — Product temperature control is monitored from the point of receipt to patient administration; systems are evaluated for effectiveness of their chosen monitoring strategy.
- **Emergency Preparedness** — There is a QMS to mitigate risk and a preparedness plan to evaluate the potential for excursions and ensure product viability in the event of a disruption. Having redundant systems and processes is the key to preparedness.

Health-system pharmacists are encouraged to convene a multistakeholder group to review the self-assessment and develop an action plan to address any identified gaps or to strengthen existing processes.

CONCLUSION

The foundation for health-systems design to optimize cold chain management is having an understanding of best practices and regulatory requirements. USP has issued extensive guidance in chapters <659> and <1079> and continues to evolve guidance on regard to risk and mitigation strategies. Health systems should have a comprehensive excursion management program that includes policies and procedures that cover staff education, drug storage, and transportation; mechanisms to identify and investigate temperature excursions; mitigation strategies; and an effective QMS. Pharmacists are well-positioned to provide leadership in cold chain management and to minimize risk to the organization and its patients.

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This resource guide is a product of the second of three invitation-only executive forums on cold chain management. The first forum focused on Cold Chain Management 101 and laid the foundation for current state that exist in hospitals and health systems. This forum focused on health-systems design to optimize cold chain management including cold chain excursion management, regulatory compliance and considerations, and facility and equipment strategies. The third event will focus on the future state including advancements in technology and innovation. ASHP looks forward to working with decision-makers and members of the interprofessional team, to continue to effectively manage supply chain needs, as well as influence regulations and technologies as they evolve. **The executive forums on cold chain management were made possible through the support of Cold Chain Technologies, Inc.**



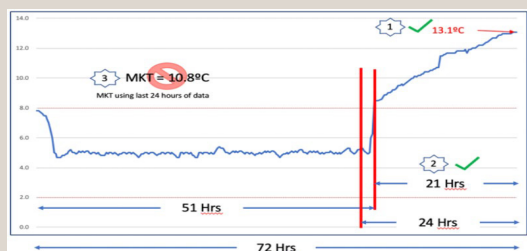
APPENDIX A

Temperature Excursion Allowances

Controlled Cold Temperature (CCT) Allowances	Controlled Room Temperature (CRT) Allowances
<ul style="list-style-type: none"> Temperature maintained thermostatically between 2 and 8 °C (36 and 46 °F) MKT¹ may be used during excursion provided <ul style="list-style-type: none"> » MKT does not exceed 8 °C (46 °F) » Excursion between 2 and 15 °C (36 and 59 °F) » No excursion below 2 °C (36 °F) or above 15 °C (59 °F) » Excursion time is no more than 24 hours CCT excursions should occur only one time during the possession of the product within the supply chain unless directed otherwise by the manufacturer. 	<ul style="list-style-type: none"> Temperature maintained thermostatically between 20–25 °C (68–77 °F). <ul style="list-style-type: none"> » MKT may be used during an excursion provided: MKT does not exceed 25 °C (77 °F) » Excursion between 15 and 30 °C (59 and 86 °F) » Transient excursions are NMT 40 °C (104 °F) » Excursion time is no more than 24 hours A <i>controlled room temperature</i> product may, alternatively, be stored and shipped in a cool place or refrigerated, unless otherwise specified in the individual monograph or on the label. Storage time in controlled cold or cool place cannot be used to calculate excursion temperature outside of controlled room temperature ranges.

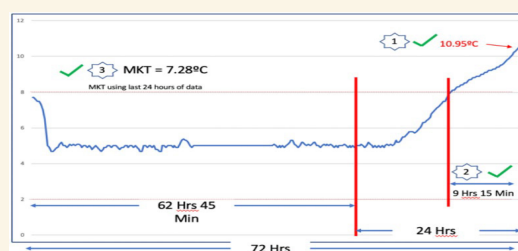
¹MKT: <1079.2> Mean Kinetic Temperature in the Evaluation of Temperature Excursions during Storage and Transportation of Drug Products. An MKT calculator can be downloaded at <https://tech-publish.com/mean-kinetic-temperature-and-temperature-excursions/>

Case Examples (Courtesy of Desmond Hunt, USP)



In this example, a refrigerated trailer making a delivery went out of CCT at 51 hours

1. The high temperature was 13.1°C ✓
2. The excursion was less than 24 hours ✓
3. The MKT was 10.88°C for the last 24 hours (outside the excursion MKT limit) ✗
4. In this case, the product should be quarantined, and the manufacturer(s) should be contacted for disposition ✗



In this example, a refrigerated trailer making a delivery went out of CCT range at 62 hours and 45 minutes

1. The high temperature was 10.95°C ✓
2. The excursion was less than 24 hours ✓
3. The MKT was 7.28°C for the last 24 hours (within the excursion MKT limit) ✓
4. In this case, the product would be considered acceptable to release to salable inventory ✓

APPENDIX B: COLD CHAIN MANAGEMENT SELF-ASSESSMENT TOOL

This self-assessment tool was created by ASHP Cold Chain Forum participants in 2022 to help hospitals and health systems manage issues regarding cold chain management.

These self-assessment questions can help your hospital and health system understand temperature-controlled distribution and process flows for temperature-sensitive pharmaceuticals, biologics, and vaccines.

For each item, please indicate your level of agreement

Do not agree at all 1 2 3 4 5 Highly agree

EDUCATION AND TRAINING

1. Staff is trained in policies and procedures for appropriate storage of medications, such as what actions to take if there is a known or suspected temperature excursion.

Do not agree at all 1 2 3 4 5 Highly agree

2. Management stays informed on and applies industry standards and trends, including product storage.

Do not agree at all 1 2 3 4 5 Highly agree

EMERGENCY PREPAREDNESS

3. Emergency preparedness policies and procedures address drug storage temperature requirements.

Do not agree at all 1 2 3 4 5 Highly agree

4. Systems are designed to reduce losses (e.g., inventory limits are set for each storage location, or products are shipped in limited quantities).

Do not agree at all 1 2 3 4 5 Highly agree

5. Regional hubs, warehouses, or other central repository are available to shift product if there is a disaster or system failure.

Do not agree at all 1 2 3 4 5 Highly agree

6. Back-up power is available with adequate capacity to support required cold chain storage.

Do not agree at all 1 2 3 4 5 Highly agree

7. If product needs to be moved to another location, back-up power supply is available.

Do not agree at all 1 2 3 4 5 Highly agree

8. There is a limit to high-cost drugs stored in smaller sites and clinics.

Do not agree at all 1 2 3 4 5 Highly agree

9. Redundancies are built into the system to minimize the impact of equipment failure (e.g., single-wide vs. double-wide refrigerators).

Do not agree at all 1 2 3 4 5 Highly agree

MONITORING

10. Temperature is monitored in conjunction with an alarm system in refrigerators and freezers where drugs are stored.

Do not agree at all 1 2 3 4 5 Highly agree

11. For critical storage locations (e.g., refrigerators and freezers), temperatures are monitored remotely.

Do not agree at all 1 2 3 4 5 Highly agree

12. When medications require transport, medication-specific storage requirements and sensitivity to excursions are considered and special storage and monitoring is used accordingly (e.g., coolers, data loggers).

Do not agree at all 1 2 3 4 5 Highly agree

13. Product temperature control is monitored at the point of receipt.

Do not agree at all 1 2 3 4 5 Highly agree

POLICIES AND PROCEDURES

14. Protocols that define what is considered an allowable temperature excursion and timeframes are in place.

Do not agree at all 1 2 3 4 5 Highly agree

15. Procedures on how to investigate and respond to a suspected temperature excursion are in place.

Do not agree at all 1 2 3 4 5 Highly agree

16. Policies and procedures that define how long unmonitored cold products can be kept outside of a refrigerator are in place.

Do not agree at all 1 2 3 4 5 Highly agree

17. Policies and procedures that define how long unmonitored cold products can be kept outside of a freezer are in place.

Do not agree at all 1 2 3 4 5 Highly agree

18. Pharmacy has oversight for appropriate temperature control in all areas where drugs are stored.

Do not agree at all 1 2 3 4 5 Highly agree

RECEIPT AND STORAGE

19. Drugs are received directly in the pharmacy and controlled from the point of receipt.

Do not agree at all 1 2 3 4 5 Highly agree

20. All drugs administered in the organization (acute and ambulatory) are received only from or through the pharmacy.

Do not agree at all 1 2 3 4 5 Highly agree

21. This pharmacy location has the appropriate storage capacity for pharmaceuticals.

Do not agree at all 1 2 3 4 5

22. Storage devices (e.g., refrigerators) are used exclusively for pharmaceuticals.

Do not agree at all 1 2 3 4 5 Highly agree

SHIPPING AND TRANSPORT

23. When using a courier service for offsite deliveries, temperatures are monitored during transit.

Do not agree at all 1 2 3 4 5 Highly agree

24. Controls are in place to maintain appropriate temperatures during transit to patients.

Do not agree at all 1 2 3 4 5 Highly agree