MedPro Group
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Checklist

Avoiding Poor Quality and Fraudulent Medical Supplies and Devices

Poor quality and fraudulent medical supplies and devices are a growing threat to patient safety in the United States and around the world. This threat has proliferated in the wake of ongoing supply chain issues in healthcare.[1] Listed as one of ECRI's *Top 10 Health Technology Hazards for 2025,* substandard and counterfeit supplies and devices can harm patients, disrupt the already tenuous supply chain, worsen product shortages, and cost organizations time and money.[2]

Tackling poor quality and fraudulent supplies and devices is challenging because the supply chain is complex, and issues can occur at any stage. These materials may result from poor manufacturing, poor quality control, tampering, diversion, or counterfeiting.[3] Addressing this persistent issue will require large-scale interventions that involve numerous stakeholders. However, at the organizational level, proactive steps can help prevent faulty supplies and devices from entering the system and wreaking havoc.

The following checklist offers high-level strategies to help organizations assess current procurement and supply chain protocols and identify potential gaps.[4]

	Yes	No
Does your organization have written due diligence policies, procedures, and checklists associated with procuring medical supplies and devices?	☐	☐
Have accountabilities for due diligence procedures been assigned, and are staff members aware of their responsibilities?	☐	☐
Does your organization procure medical supplies and devices from known and trusted manufacturers or distributors?	☐	☐
When possible, does your organization avoid purchasing medical supplies and devices from online consumer websites?	☐	☐

	Yes	No
Has your organization established thorough criteria for evaluating suppliers and distributors, including:		
• History and experience?	☐	☐
• Reputation, including letters of recommendation or testimonials?	☐	☐
• Safety and quality standards?	☐	☐
• Physical location and any associated vulnerabilities?	☐	☐
• Compliance with regulatory and professional standards?	☐	☐
• Relevant licenses, registrations, certifications, and inspections?	☐	☐
• Credentials and training processes?	☐	☐
• Technical and physical safeguards?	☐	☐
• Quality control and quality assurance processes and procedures?	☐	☐
• Documentation processes?	☐	☐
Has your organization identified factors that could be red flags during the evaluation process (e.g., lack of transparency, inability to produce necessary documentation, inadequate staffing, and previous criminal or civil penalties)?	☐	☐
Does your organization conduct and document routine audits of suppliers to verify compliance with quality, safety, and regulatory standards?	☐	☐
Does your organization contract with testing organizations to verify the functionality and safety of equipment and supplies?	☐	☐
Has your organization established internal testing and approval procedures for new supplies and devices that are not validated externally?	☐	☐
Does your organization select supplies and equipment that come with tamper-resistant features or packaging (e.g., seals, bands, labels, and closures)?	☐	☐
Are healthcare providers and staff members asked to provide feedback on the quality of medical supplies and equipment?	☐	☐

	Yes	No
Are mechanisms in place to enable tracking of all supplies and devices within the system (e.g., serial numbers, barcodes, RFID, etc.)?	☐	☐
Does your organization have a well-designed process for reporting substandard, defective, or suspicious medical supplies and devices both internally and to appropriate authorities?	☐	☐
Is a process in place to immediately sequester supplies or devices with known or suspected quality issues?	☐	☐
Do individuals who are responsible for managing contracts and relationships with distributors and suppliers maintain appropriate oversight?	☐	☐
Does your organization educate the workforce about supply chain issues, strategies for spotting poor quality or fraudulent materials, and appropriate reporting protocols?	☐	☐

Resources

- ECRI: Combating Substandard and Counterfeit Medical Devices
- Health Care Science: Rethinking Counterfeit Medical Supply Chains: A Critical Review of the Current Literature
- Michigan State University Center for Anti-Counterfeiting and Product Protection: Assessing the Risks of Counterfeiting and Illicit Diversion of Health Care Products
- Security: Protecting Hospitals From Supply-Chain Counterfeits and Other Security Threats
- World Health Professional Alliance: Be Aware: Helping to Fight Counterfeit Medicines, Keeping Patients Safer

Endnotes

[1] ECRI. (2025, March 13). *Combating substandard and counterfeit medical devices.* Retrieved from https://home.ecri.org/blogs/ecri-blog/combating-substandard-and-counterfeit-medical-devices; Albiani, R. (2021). Combating counterfeit medical devices: A case study. *Brand Protection Professional, 6,* 1. Retrieved from https://bpp.msu.edu/magazine/combating-counterfeit-medical-devices-a-case-study-march2021/

[2] ECRI. (2025). *Executive brief: Top 10 health technology hazards for 2025.* Retrieved from www.ecri.org

[3] World Health Organization. (2024, December 3). *Substandard and falsified medical products.* Retrieved from www.who.int/news-room/fact-sheets/detail/substandard-and-falsified-medical-products; International Council of Nurses. (2023). *Position statement: Substandard and falsified medical products.* Retrieved from www.icn.ch/sites/default/files/2023-04/PS_E_Substandard_and_Falsified_Medical_Products_0.pdf

[4] This checklist is based on information from the following sources: ECRI, *Combating substandard and counterfeit medical devices;* ECRI, *Executive brief: Top 10 health technology hazards for 2025;* Trent, C. (2013). *Assessing the risks of counterfeiting and illicit diversion of health care products.* Michigan State University Center for Anti-Counterfeiting and Product Protection. Retrieved from https://a-capp.msu.edu/article/assessing-the-risks-of-counterfeiting-and-illicit-diversion-of-health-care-products/; Clayman, N. (2023, May 5). *The real problem with counterfeit medical products.* Exponent. Retrieved from www.exponent.com/article/real-problem-counterfeit-medical-products; Alpha Health. (2024, September 25). *The essential checklist for evaluating medical equipment vendors: A practical guide for buyers.* Retrieved from https://alphahealth.ae/the-essential-checklist-for-evaluating-medical-equipment-vendors/medical-equipment/; MedPro Group. (2025 [last updated]). *Checklist: Due diligence of business associates.* Retrieved from www.medpro.com/documents/10502/2899801/Checklist_Due+Diligence+of+Business+Associates.pdf

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