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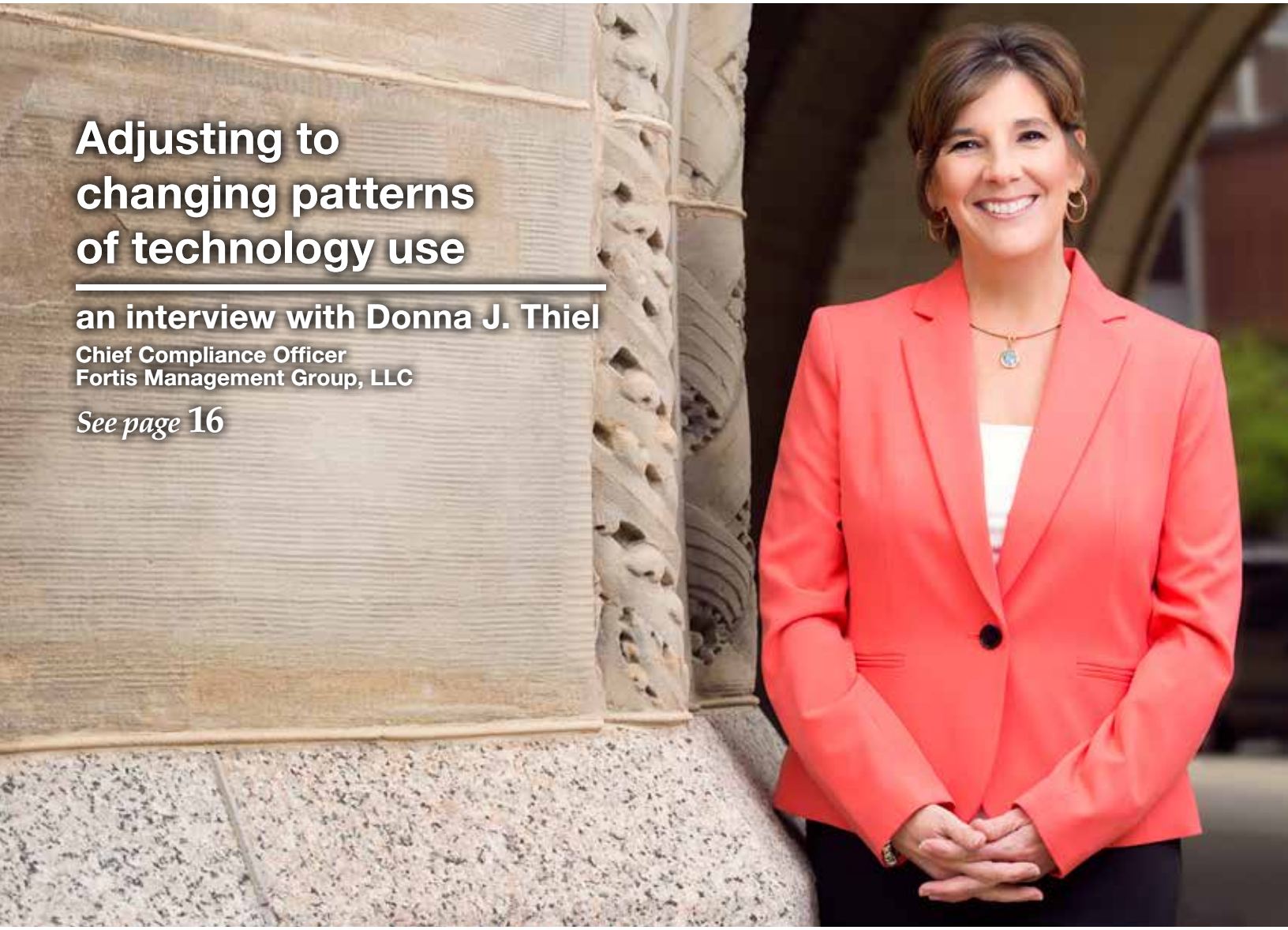

Adjusting to changing patterns of technology use

an interview with Donna J. Thiel

Chief Compliance Officer
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by David Silva, JD, CHC, CPHQ

Temperature monitoring: A primer for compliance officers

» Take routine account of documentation and record keeping to ensure both that vaccines and drugs are stored properly and that the process is memorialized.

» Conduct physical inspections and assessments of pharmaceutical storage areas.

» Provide education and training regularly for everyone who may handle pharmaceuticals.

» Emphasize the reality that everyone plays a role in keeping vaccines and medicines safe and safe to use.

» Discern trends and patterns in storage and use, and make a policy for discarding improperly stored vaccines and medicines.

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Even before the advent of the Affordable Care Act (ACA), healthcare was the most heavily regulated industry in the United States. Today, in the post-ACA–implementation environment, healthcare regulation has become even more stringent. Such regulation is both logical and necessary, because healthcare is intensely personal and, obviously, often a matter of life and death.

Silva

Given the scrutiny, the stakes, and the complexity that define the healthcare landscape, it's no surprise that a wide variety of risks abound. But what is surprising is the proliferation of risks related to the basic maintenance of physical assets—risks that may seem bizarre in an advanced healthcare system. For instance, maintaining drugs and vaccines at their proper temperatures is, of course, essential for both effective and safe healthcare delivery. Nevertheless, improper handling or storage of pharmaceuticals designed to treat certain conditions and of vaccines that prevent certain illnesses is not uncommon, and it can compromise sterility and efficacy, which can, of course, jeopardize patient safety and lead to patient harm.[1]

In its meticulous research on this topic, the World Health Organization noted that:

> More than two million deaths were averted by immunization, and as well as an additional 600,000 hepatitis-B-related deaths, that would otherwise have occurred in adulthood [citation omitted] … attributable to work of national immunization programmes. However, despite this, more deaths could be prevented, and illnesses avoided, if vaccines which are sensitive both to excessive heat and excessive cold, were transported and stored correctly.[2]

Regulators have begun to take notice of these risks. Federal and state agencies have issued fines and sanctions, including threatened hospital closures, when there is evidence of an institution's inability to maintain pharmaceuticals and vaccines at proper, safe temperatures. For instance, in one California hospital, more than 4,000 patients were administered vaccines that the hospital knew

had been frozen and thus were no longer efficacious. Two patient deaths were imputable to this fatal error in operations and in judgment. The state regulatory agency cited a violation of state law[3] and found the hospital posed an "immediate jeopardy" to its patients. More specifically, the state agency cited to the law's subsection (c), which provided in pertinent part that "'immediate jeopardy' means a situation in which the licensee's non-compliance with one or more requirements of licensure has caused, or is likely to cause, an immediate jeopardy or death to the patient."[4] The state threatened the hospital with closure absent quickly devised, implemented, and effective remedial measures. The state regulatory agency levied significant monetary fines, and the families of those who died asserted monetary claims against the hospital.

Why should Compliance be concerned?

Given the myriad consequences of failing to maintain best practices in the compliant storage and administration of vaccines and pharmaceuticals, chief compliance officers (CCOs) are among those with the most at stake. Regulator-issued fines for non-compliance certainly are undesirable; regulator-issued fines for preventable events represent merely the tip of a nightmarish iceberg that has much greater consequences and negative impact to patients, their families, and medical professionals alike.

Additionally, there is an ever-accelerating trajectory toward a confluence of quality-of-care delivery services and compliance with established rules and leading practices; this presents a most valid reason for the Compliance Office to be actively engaged in the compliant storage and administration of vaccines and pharmaceuticals. Furthermore, in all likelihood, the potential for personal liability for CCOs will only increase in the future as the penalties and media attention around instances of non-compliance continue to grow. A facility's failure to adhere to standards in the storage of these valuable products can be viewed as a multilateral breakdown. Also, the reputational consequences that may arise from a patient safety event resulting from insufficient maintenance of physical assets are growing, and leading CCOs are identifying opportunities to be more involved in oversight.

Another aspect of these issues that directly impacts the Compliance Office is that of preventing waste and abuse. Once Operations detects, or the Compliance Office learns, that the sterility and/or efficacy of vaccines or pharmaceuticals have been compromised, all must arrange for their proper discard and replacement. Because this replacement consumes valuable organizational financial assets, it constitutes preventable waste. Arguably, if such an issue were to recur, and thus become a trend, such recurrences collectively could be viewed as abuse. These waste and abuse implications should be prominent areas of concern for the Compliance Office. Because asset protection and temperature monitoring encompass anti-fraud, anti-waste, and anti-abuse (anti-FWA) and care delivery compliance, CCOs and their reports should not only familiarize themselves with the issues and the compliance pitfalls in this very important area of compliance, but also be prepared to act, and act with consistency.

In addition to the Compliance Office, several groups of stakeholders also have a vital interest in the proper storage and administration of safe pharmaceuticals and vaccines:

- **Patients:** With their confidence in the ability of hospitals and even medical professionals eroding, patients want to know that injections and drugs are stored properly and are both safe and effective.
- **Medical professionals:** Professionals want to uphold the Hippocratic Oath, and they expect their actions will help improve patients' health.

- **Medical institutions:** The negative media and legal liability that can surround failure to deliver safe drugs and vaccines is a significant concern for hospital administrators.
- **Chief financial officers:** CFOs want to avoid what could be debilitating hits to their bottom lines, due to the administration of improperly stored or unsafe pharmaceuticals and vaccines.[5]
- **Pharmaceutical manufacturers:** Manufacturers would like to avoid the negative publicity that an incident associated with their drugs would cause, even if they are not directly responsible for the contamination or improper administration of their products.
- **Regulators:** Federal and state agencies have issued fines and sanctions, including threatened hospital closures, based on institutions' inability to maintain pharmaceuticals and vaccines at proper, safe temperatures.[6,7] Furthermore, in addition to the Office of Inspector General's seven elements of an effective compliance program, the Centers for Medicare & Medicaid Services favors—and the federal government requires—implementation of anti-FWA programs in several contexts.[8] Moreover, refrigerators, along with biomedical and other healthcare devices, are high cost, highly sought after, and highly susceptible to theft.

Establishing a proper environment: The basics

Across the continuum of care, companies develop, test, and manufacture vaccines and pharmaceuticals to achieve the goals of preventing illness and providing remedies for maladies. Those vaccines and pharmaceuticals must then be stored and handled in accordance with manufacturers' recommendations. Generally, safe practices include correct storage at proper temperatures, and this is where compliance, engineering, and procurement professionals come in.

Planning for refrigeration: Not as simple as it may seem

The foregoing individuals are among those charged with maintaining a safe environment of care. In this context, a hospital must manage its medical equipment risks.[9] It also must inspect, test, and maintain its medical equipment, including its refrigerators. Proper refrigeration begins with research, planning, commitment, and accountability, which are valuable but sometimes rare commodities. In general, anticipating and creating projections for capital expenditures, equipment, and maintenance needs are not easy tasks. And, in the healthcare industry in particular, an array of obstacles can impede refrigeration compliance, many of which arise for a variety of justifiable reasons based on unavoidable realities. For instance, refrigeration compliance involves participants from multiple departments and multiple disciplines, who may not have strong relationships. Furthermore, changing compliance policies generally requires a great deal of time and effort, particularly in the absence of a pressing obvious catalyst for change (i.e., "If it ain't broke, don't fix it").

So, from an organizational standpoint, doing the right thing isn't always easy. For compliance, engineering, and procurement professionals, the first consideration is to minimize the risks both to and from power sources. Is the electrical infrastructure of the medical center, clinic, or medical office building reliable? For instance, see the specific requirements that apply in the hospital context in TJC's Environment of Care standards; these are similarly instructive and provide excellent guidance for non-hospital facilities. Even assuming the building was constructed in accordance with relevant

codes, engineering and procurement professionals should evaluate the sufficiency of their responses to the following questions:

- Have you tested the adequacy of your electrical hardware and infrastructure?
- Have necessary repairs been postponed?
- Have there been electrical code changes that you know or suspect will require upgrades?
- Is there a plan to maintain vaccines and pharmaceuticals at their proper temperatures in the event of a power interruption or loss? Is everyone aware of that plan?
- Is your plan comprehensive or merely ad hoc?
- Are your plan's components sufficiently synthesized to interact seamlessly?
- Do you regularly and routinely search for weaknesses or dependencies?
- How are identified weaknesses or dependencies corrected—with proper alacrity or only when budget allows?

Engineering and procurement professionals—and compliance professionals—will gain a clearer picture of their facilities' level of infrastructure and preparedness, based on their responses to these questions. After the development of a thorough, current-state assessment, a road map for infrastructure and strategy enhancements can follow.

Getting the right equipment in place

Once engineering and procurement professionals have attended to and rectified infrastructure and strategy issues, they must then attend to matters of capital acquisition, because temperature compliance depends directly on acquiring and maintaining the right equipment. To achieve and sustain compliance, it is absolutely paramount to also establish clear lines of communication and solid coordination between the Engineering and Procurement departments and among all other relevant business units; to wit:

- Engineering and the affected business unit must coordinate with Procurement regarding new equipment.
- Engineering must communicate with Procurement on the development of a business case for capital acquisition or the need for infrastructure improvements.
- All stakeholders must designate, gain consensus on, and oversee accountabilities and the division and coordination of duties.
- Compliance must coordinate with the aforementioned departments and professionals to identify and prioritize weaknesses and to conduct routine assessments.

Thoughtful discussion and extensive research should precede the acquisition of new equipment. The following steps outline a general process for new-equipment acquisition:

- **Conduct research.** All stakeholders should investigate the equipment and manufacturers that would satisfy business units' refrigeration needs.
- **Identify, engage, and gauge.** Who will use the equipment? Personnel, logistical, and maintenance considerations are primary concerns.
- **Anticipate and project.** Strategy is paramount. Getting all stakeholders to review current refrigeration needs regularly, project future needs, and communicate those needs is an important step in the process. Waiting until capital assets are excessively aged, broken, or unrepairable before acting is not a strategy.
- **Coordinate with Finance.** Once the stakeholders have communicated projected refrigeration needs, all must be made aware of—and must adhere to—budgets, capital cost guidelines, and timelines.

Stakeholders should seek universal buy-in and establish a procedure with Finance with a view to streamlining the process.

- **Solicit the best price.** Are there impediments in the acquisition process, including any bid or request-for-proposal requirements? Do supply chain purchasing organizations offer any discounts or ways of facilitating the process?
- **Acquire.** Does the contracting process need a review? If the contract includes preventive maintenance, what are the exact stipulations? What is the duration of the contract?

Preventive maintenance: Not to be overlooked

Preventive maintenance may be the weakest non-human factor link in the chain of temperature control, because business unit leaders invariably trim preventive maintenance budgets when faced with financial constraints. Although this approach may seem logical from a budget perspective, it is an imprudent strategy, because in the event of a regulator inquiry, one of the document sources that regulators routinely request is a manufacturer's required preventive maintenance schedule. Regulators are checking whether the hospital, clinic, or medical office building actually adhered to the stipulated schedule. This is a bellwether for compliance professionals. Compliance must be involved and play a role throughout these processes.

Once the hospital, clinic, or medical office building has acquired the refrigerator or other device, business unit leaders—with Engineering, Procurement, and Compliance involvement—should treat the acquisition as they would *any* capital investment—with all due attention that will prolong its useful life as long as possible. Such treatment ought to entail:

- **Education and training.** Engineering—in tandem with the manufacturer if possible—should conduct an education and training program on how to properly use and not abuse the new acquisition.
- **Preventive maintenance.** With which business unit should responsibility for preventive maintenance lie? Once consensus has been reached on this question, the next step is the establishment of the duties of scheduling and payment, if relevant, as well as the establishment of a centralized repository for preventive maintenance schedules and logs of such maintenance.
- **Equipment list.** Whether centralized or decentralized, the hospital, clinic, or medical office building should create and maintain a list of all capital assets and then implement a process for updating the list when any new refrigerator or other device is acquired.

The role of Compliance in these endeavors is to provide oversight, coordinate efforts, and make recommendations whenever necessary. To abdicate these duties would invite a host of problems that compliance professionals could avoid—and for which regulators would demand answers.

Maintaining control of valuable assets

Just a reminder about expensive capital equipment: Although anti-FWA efforts should be robust and coordinated throughout any hospital, clinic, or medical office building, the intrinsic value of medical-grade refrigerators and biomedical equipment requires heightened vigilance and protection which, at a minimum, should include:

- **Identification of the high-risk or high-value assets.** This process necessarily should take into account the device's portability or lack thereof.
- **Asset-protection measures**, such as:
  - Clear procedures for asset storage when the asset is not in use;
  - Development and wide circulation of procedures (including training) governing the proper use—and proscriptions on abuse—of assets;

- Uniform and well-publicized disciplinary actions that will be taken for violations of said procedures; and
- Consideration of remote monitoring, whether through radio-frequency identification or bar code technology.

Key takeaways amplified

Safe and effective drugs and vaccines are essential throughout the continuum of care. Their proper storage and administration depend on the right equipment. Medical-grade refrigerators and biomedical devices constitute an enormous investment for any healthcare institution. Research, education, training, and maintenance, as well as anti-FWA steps are important components of a comprehensive temperature-monitoring and compliance regimen.

The following are some key takeaways for CCOs and for leaders in Engineering, Procurement, and relevant business units to act on.

Take routine account of documentation and record keeping

When it comes to any capital investment, hospitals, clinics, and medical office buildings cannot afford to "invest and forget." Compliance should, at a minimum, provide oversight vis-à-vis audits. If need be, Compliance should be prepared to assume primary responsibility for auditing.

Conduct physical inspections and assessments

Periodic review of the physical office and storage space is necessary for adherence to policies and procedures—including whether any otherwise unaccounted-for refrigerators or devices have appeared or, once present, whether any refrigerators or devices have disappeared! Again, the role of Compliance can be tailored to be as active as the facility and its resource may require.

Engage all in education regularly

Irrespective of the forum or format (e.g., formal training, brown-bag lunches, or e-newsletters), routine reminders of everyone's responsibility for capital assets are always advisable.

Emphasize the reality that everyone plays a role

Whether it's Neonatal, Pathology, or another area or department, everyone is a participant in this process. Professionals from *all* segments of healthcare have relevant, empirical knowledge and data to contribute to an organization's capital acquisition and management methodology. Convening representatives from multiple disciplines is essential and is a duty that Compliance may logically lead. Be sure to seek out lots of voices and lots of views. When in doubt, err on the side of over-inclusivity.

Discern trends and patterns

CCOs, take note—although weaknesses may exist in this context, persistent weaknesses lead to trends. Trends of weaknesses may portend larger, more systemic compliance problems. Always view compliance issues through a lens that is as objective as possible. Only then will compliance be able to discern whether weaknesses in medication and vaccine refrigeration prove to be a harbinger of broader compliance failings.

Final thoughts

To effectively navigate this increasingly complex environment, CCOs should take a proactive approach and partner with Engineering, Procurement, and other key stakeholders to incorporate governance and

oversight processes around asset protection and temperature monitoring.

Throughout all stages of asset acquisition and maintenance, always remember: Communication, communication, communication—both externally with utilities, providers, and regulators, and internally with company stakeholders—will go a long way toward achieving and ensuring vaccine and pharmaceutical safety, asset protection, and temperature monitoring compliance.

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2. World Health Organization: "Temperature Sensitivity of Vaccines" 2006, page ix. Available at http://bit.ly/1TVdQ3x.
3. See then iteration of California Health & Safety Code section 1280.1.
4. Id. at Section 1280.1(c)
5. MS Welte: "Vaccines ruined by poor refrigeration" *Washington Post*, December 4, 2007. Available at http://wapo.st/1Xc0DGq.
6. See 42 CFR 483.60(d),(e)
7. KJ Frank: "Monitoring temperature-sensitive vaccines and immunologic drugs, including anthrax vaccine" Am J Health Syst Pharm 1999;56:2052-5. Available at http://bit.ly/1TOQJcX.
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9. The Joint Commission: Standard EC.02.04.01 and Standard EC.02.04.03: Tips for meeting the revised equipment maintenance standards. Available at http://bit.ly/1TVenme