

"We Are Sorry to Have to Inform You"

All seemed well at a busy pediatric practice until a routine audit conducted by the Vaccine for Children program (VFC). When the VFC auditor reviewed the temperature log for the practice's vaccine storage unit, numerous temperatures were noted to be out of conformity with guidelines. Non-conforming temperatures had been recorded sporadically over approximately a nine month period, during which a significant number of children had received standard pediatric immunizations. VFC notified the Centers for Disease Control, and the practice promptly took appropriate remedial actions.

The practice's vaccine storage unit was a combo cooler, with a refrigerator compartment and a freezer compartment, each monitored by a temperature probe connected to a battery operated thermometer mounted on the exterior of the unit. (Each cooling compartment also had a thermometer affixed to its inner wall, but data from those devices was not routinely noted, because they indicated temperature in Centigrade, while the temperature log called for readings in Fahrenheit.) A temperature log was kept, noting a refrigerator range of 36 to 42 degrees Fahrenheit and a freezer setting of 5 degrees. Readings were to be taken twice daily but often were logged only once. During the months in question, logged temperatures were unpredictable and variable, with non-conforming refrigerator readings on some days and non-conforming freezer readings on other days, with rare overlap. The log was counter-signed by a physician, and non-conforming readings were reportedly brought to the attention of the practice administrator (soon to be ex-administrator), but other than occasional adjustments to the unit's settings, no action was taken to identify the cause of the concerning temperatures.

Following the VFC audit, the practice replaced its vaccines. It also purchased a new thermometer for the refrigerator and a separate one for the freezer. Interestingly, the new thermometers consistently indicated temperatures within guidelines, while the old thermometer continued to show non-conforming readings, indicating the likelihood that the culprit was the thermometer itself or perhaps its battery, rather than the refrigeration unit. Nonetheless, because of the many logged temperatures outside of guidelines over such a long period of time, the practice, with legal advice and in consultation with the CDC, elected to notify all patients who had received vaccines potentially rendered ineffective by storage temperatures outside of manufacturer recommendations. A "Dear Parents" letter was composed, beginning, "We are sorry to have to inform you ..." and explaining the recommendation for re-vaccinations, to be provided free of charge. The re-vaccination program was completed uneventfully but at considerable cost to the pediatric practice.

Things could have been worse. In January 2017, New Jersey's Medicaid Fraud Division temporarily suspended a pediatrician and his practice from that state's Medicaid programs, based upon findings that the practice had improperly stored vaccines administered to children as part of the VFC program. The suspension was later lifted, based upon a

settlement that included modification of certain office practices and a very substantial monetary penalty.[1] An isolated incident? As to the penalties, perhaps. As to proper storage of vaccines, perhaps not. In June 2012, the Department of Health and Human Services issued a report describing “vulnerabilities in vaccine management” in 76% of the 45 VFC participating practices selected for screening. The report cited deficiencies as to storage temperatures, storage of expired vaccines with unexpired vaccines, and adequate documentation.[2] To borrow a quote from the political realm, “Nobody knew health care could be so complicated.”

Some medication safety issues are more obvious than others. This article illustrates one issue which may tend to fly beneath the radar but which can have very serious implications for patients, physicians and practices. Following are two links to CDC information and materials that may help your practice avoid the pitfalls described.

<https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf>

<https://www.cdc.gov/vaccines/hcp/admin/storage/index.html>

[1] Press release, Office of the State Comptroller, Medicaid Fraud Division, May 2, 2017

[2] Department of Health and Human Services, Office of Inspector General, “Vaccines for Children Program: Vulnerabilities In Vaccine Management,” June 2012

The contents of The Sentinel are intended for educational/informational purposes only and do not constitute legal advice. Policyholders are urged to consult with their personal attorney for legal advice, as specific legal requirements may vary from state to state and/or change over time.