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Case Studies

Complying with USP 797 *Progress Profile of Swedish Medical Center*

Swedish Medical Center is the largest, most comprehensive, non-profit health provider in the Pacific Northwest. In addition to general medical and surgical care, Swedish is known as a regional referral center, providing specialized treatment in areas such as cardiovascular care, cancer care, orthopedics, high-risk obstetrics, neurological care, sleep medicine, pediatrics, organ transplantation and clinical research.

Founded in 1910, Swedish now has more than 7,000 employees and a medical staff of more than 2,000 physicians, most of whom are private practitioners. Swedish encompasses three hospital campuses (697-bed First Hill campus, 385-bed Providence campus, and 163-bed Ballard campus) totaling 1,245 licensed beds, a new community-based emergency room and specialty center in Issaquah, Swedish Home Care Services and Swedish Physicians – a network of 12 primary-care clinics located throughout the Greater Seattle area.

When USP Chapter <797> was released in 2004, the Swedish inpatient pharmacy IV admixture services mirrored those in about 95% of the country. While Swedish had produced millions of high-quality doses over the years, they were not in compliance with the new regulations. Swedish began to formulate a strategy to become compliant almost immediately after USP 797 was finalized. A committee was formed and chaired by Jay Stacy, RPh, IV Lead Pharmacist at the main First Hill campus.

Getting Started

One of their first tasks was to meet with Stan Jeppeson of the Washington State Board of Pharmacy. At the time, the Board had not formally adopted USP 797, but was highly supportive of the concept. Swedish had a long history of collaborative work with the Board on inpatient pharmacy standards. Both entities felt they could learn together as the implementation process evolved.

The next step was to look for outside expert help beyond just reading what had been written in the pharmacy literature. One helpful resource was the three-day APEx training offered by Eric Kastango of Clinical IQ and Jim Wagner. Eric and Jim are both on the USP 797 panel and are nationally well-known from their writing, speaking and consulting activities.

IV Lead Technician Cliff Larrieu attended one of the first APEx training sessions in Allentown, PA. Cliff learned a tremendous amount about a number of scientific disciplines relevant to USP 797. He also brought back policy and procedure templates to help start the revision of the paperwork and training processes.

Dan Murphy, RPh, former head pharmacist in the Swedish home care division pharmacy, started the policy and procedure revision process. Working in a facility that was already operating in basic compliance with USP 797, Dan was

able to incorporate existing home care documents, the current extensive inpatient manual and Clinical IQ templates to build a comprehensive policy and procedure manual that would meet the new regulations.

Jay and Cliff reevaluated their entire training program. The training had been good, but there were still important gaps for Swedish to fill for USP 797. With so many other tasks to complete, a decision was made to buy the Valiteq System for a relatively small additional expense. Other ready-to-use quality training options are available. More information on the Valiteq offering can be found at www.valiteq.com.

Gaining Support from Leadership

Of course, the new facility needs were a major financial and logistical issue because the Swedish inpatient facilities did not have USP 797-compliant cleanrooms. The challenge for pharmacy administration was to begin immediately to educate upper hospital administration on the new regulations and their costs. It was clear from the outset that significant capital expenditures would be required.

Six years ago, Swedish chose Cardinal Health to manage their pharmacies. David West, RPh has worked at Swedish since 1977 and is now the System Director of Pharmacy for all three Swedish pharmacies. According to West, compliance with USP 797 is “the right thing to do” and is completely consistent with the Cardinal Health objective of improving drug delivery quality.

Determining What to Build

Committee members went on site visits to other USP 797-compliant inpatient pharmacies. While such facilities are still in the minority, they do exist all over the country. Use your professional contacts to find willing hosts in your geographical area.

Additional individualized expert help came by contacting Eric and Jim from Clinical IQ to act as paid consultants in the physical facility remodel. There are many options for getting help on physical plant changes but even the experts will recommend that the “buyer beware.” Swedish decided to go with the people helping to draft the regulations to assure the optimum results

The story of what Swedish will build is as complex as the different pharmacy services within the system. The answer can be summed up in that a plan was developed specific to the needs of each area. First, there would be a compounding center to serve the entire system for non-immediate-use doses. In addition, the First Hill site would have a new fully compliance “first dose” center. The First Hill pediatric pharmacy and Providence site would have fully compliant admixture rooms. The Cancer Center and Ballard sites would have pharmacies that prepared only “immediate use” doses and would be supported by the compounding center as needed.



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Summary

The Swedish Medical Center case study demonstrates that there are many ways to comply with USP 797. Different strategies may be employed in small, medium and large settings, depending on resource and space constraints. There are additional resources available to help in compliance far beyond those mentioned above. The process at Swedish is not yet complete, but their target of completion by the end of 2007 appears to be on track (spring 2006).

For More Information:

To learn more about Swedish Medical Center, visit www.swedish.org.

For information on Cardinal Health, visit www.cardinalpps.com.

For details on Clinical IQ, visit www.clinicaliq.com.

For information on Baxa products contact Customer Service at 800.567.BAXA (2292), or visit www.baxa.com.

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