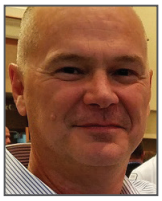
CASE STUDY

PIEDMONT HEALTHCARE AND WASTE MANAGEMENT'S PHARMECOLOGY® SERVICES COLLABORATE TO ENSURE USP <800> COMPLIANCE

Piedmont HEALTHCARE



Skip Lynch, RPh
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Outpatient Pharmacy Services
~ Piedmont Athens Regional

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OVERVIEW

Back in 1905, Dr. Ludwig Amster and Dr. Floyd Wilcox McRae founded Piedmont Hospital. At that time, they were considered pioneers in patient care, fulfilling the healthcare needs of patients all over Atlanta and surrounding communities.

Fast forward to 2021, and Piedmont Healthcare is still a recognized leader in delivering expert care. In fact, Piedmont now cares for 2.7 million patients across 800 locations, serving communities that comprise 70% of Georgia's population. What began as a single hospital more than a century ago has grown into an integrated healthcare system of 11 hospitals, 34 urgent care centers, 25 QuickCare locations, and 555 physician practice locations.

There is no question that Piedmont is committed to continuous improvement and making a positive difference in every life they touch. Building their reputation of excellence and enhancing services is a top priority. And this mission holds true with regards to hazardous waste and hazardous drug management.

"When the USP <800> standards were first published, we wanted to comply on a system-wide level," explains Skip Lynch, Piedmont's director of outpatient pharmacy services. "So we searched for a solution that could serve our entire healthcare system. PharmEcology not only offered a comprehensive solution, but provided us with a very strong partnership that would allow us to meet our specific needs."

With the help of PharmEcology's USP <800> Consultation Program, Piedmont is well on its way to protecting all healthcare personnel from hazardous drugs as well as ensuring a safe and healthy environment.

TACKLING CHALLENGES

According to numerous studies, acute and chronic health effects can occur from occupational exposure to more than 200 hazardous drugs (HDs) commonly used in healthcare settings.

As a result, the National Institute for Occupational Safety and Health (NIOSH) defined criteria for identifying these hazardous drugs. Based on this information, the United States Pharmacopeia (USP), an independent, scientific nonprofit organization, developed the USP General Chapter <800> standards for handling hazardous drugs to minimize the risk to public health. The goals of these standards include:

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- Helping to increase awareness.
- Providing uniform requirements regarding the management of hazardous drugs.
- Reducing the risk posed to patients and the healthcare workforce.

Specifically, this chapter describes the responsibilities of personnel handling hazardous drugs; facility and engineering controls; procedures for deactivating, decontaminating, and cleaning; spill control; and documentation. The standards apply to all healthcare personnel who receive, prepare, administer, transport, or come in contact with hazardous drugs and the environments in which they are handled.

PHARMECOLOGY'S USP <800> CONSULTATION PROGRAM

In order to help healthcare organizations understand the difference between the handling of hazardous drugs and managing the disposal of hazardous waste pharmaceuticals, PharmEcology created the USP <800> Consultation Program.

"In addition, PharmEcology assists organizations in creating their HD list and conducting their Assessment of Risk of HDs by taking advantage of our robust pharmaceutical database, which maintains information specific per NDC for hazardous drug handling and hazardous pharmaceutical waste disposal," explains Monica Livingston, PharmEcology's senior program and implementation manager. "We supported Piedmont's compliance with USP Chapter <800> through the use of project management and functional risk minimization tools."

She adds, "Navigating the complex regulations for handling hazardous drugs and pharmaceutical disposal can be extremely time-consuming and confusing. PharmEcology has developed tools and programs to help organizations not only stay up to date and compliant, but to also implement best practices when it comes to disposing of pharmaceutical waste and handling hazardous drugs."

The first step in the process began with Piedmont providing a data file of their 12-month purchase history of all pharmaceuticals, including NDC, generic name, brand name, dosage form, and manufacturer.

PharmEcology analyzed this data based on their proprietary NIOSH hazardous drug handling database algorithms. This resulted in a comprehensive analysis that included a list of all current NIOSH hazardous drugs (at the NDC level) and an initial Assessment of Risk, incorporating the recommendations for Personal Protective Equipment (PPE) based on USP <800> requirements and recommendations by NIOSH.

The PharmEcology team then met with Piedmont's pharmacy leadership and members of Piedmont's USP <800> team, made up of pharmacists, pharmacy techs, and nursing staff.

"The objective of these on-site visits was to discuss the details surrounding the standards of USP Chapter <800>, the differences and similarities between hazardous drugs and hazardous pharmaceutical waste, the design and objectives of our consulting program, and how our database interfaces with Piedmont data and supports their activities to meet compliance," explains Kathy Skibinski, PharmEcology's manager of regulatory and compliance.

She adds, "In addition, we held workshops on how to use proprietary PharmEcology USP <800> Consultation tools and shared information, guiding Piedmont to engage their USP <800> team in discussions related to requirements of their personnel for using PPE to minimize their exposure to hazardous drugs. This was an important step because staff needed to understand exactly what type of PPE was required of them during the preparation and administration phases of handling hazardous drugs."

Next, Piedmont discussed their operational approach to minimize risk of exposure to these hazardous drugs by their employees — and how that was reflected in their PPE requirements

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during the preparation and administration of hazardous drugs. These requirements are influenced by the type and extent of handling and manipulation of HDs during these activities, as well as the HD itself and dosage form. Hence, an analysis of data at the NDC level is necessary.

The data analysis, coupled with on-site visits, allowed Piedmont to customize their Assessment of Risk for current and future drug data. "This Assessment of Risk enables Piedmont to make decisions on the proper usage of PPE and containment strategies," explains Livingston.

"After giving PharmEcology access to our files, they took the data and applied it to their extensive database," explains Lynch. "The result was a comprehensive list of about 400 medications. We then created three risk levels, which we further defined with PPE requirements based on the drug, dosage form, and handling per staff type." These decisions are now customized and applied to future HDs added to Piedmont's formulary via the PharmEcology USP <800> Portal.

In addition to the data analysis, each client has several proprietary tools available to them via the PharmEcology USP <800> Portal. The Functional Risk Minimization tool provides a list of all types of personnel who have the potential to be exposed to hazardous drugs and summarizes all phases of hazardous drug handling, from receipt to disposal. These factors, coupled with a list of potential actions that may be taken to protect employees, helps the organization justify decisions in their Assessment of Risk process.

The last tool to be implemented was PharmEcology's Comprehensive Compliance Management Document, which itemizes all of the required standards of USP Chapter <800>. It serves as a project management tool that assigns project tasks to individuals, charts progress, and documents support of completion toward USP <800> compliance.

"PharmEcology's tools and programs have been extremely helpful in keeping us compliant," explains Chelsea Parry, Piedmont's oncology pharmacist specialist. "Because Piedmont is such a large healthcare system, we depended on PharmEcology's web-based portal to keep us organized and on task during the daunting process."

NEXT STEPS

While the identification and assessment phase is complete, Piedmont is currently working on the next phase, which includes rolling out the new changes, as well as developing and implementing training for all staff.

"Our first phase is complete — for now. However, the project is essentially ongoing because NIOSH consistently adds new drugs to their hazardous list," says Lynch. "In fact, normal-use drugs that we've been using for the past 50 years — such as the blood thinner, Coumadin — are now being considered hazardous. Basically, USP <800> has forced the industry to take a closer look at drugs that were historically considered to be normal use. But these drugs are now being carefully examined and categorized as potentially harmful to staff and patients."

Adds Parry, "When we began this project, we had no idea what was involved. We were not prepared for the extensive amount of analyzing and sequencing work that was required by USP <800>. But PharmEcology provided us with a unique tool that helped simplify the complex process. They also worked closely with us, helping us navigate each step of the project. We consider them to be a true partner."

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