NHIA
National Home Infusion Association

AS WE SEE IT

Safeguarding Patient Safety

By Tyler Wilson

Because ensuring patient safety is a top priority for the home infusion industry, the topic of sterile compounding is especially important to members of our community. Today, more than ever before, pharmacies are under a microscope. Home and specialty infusion providers must ensure that the processes used in compounding and administering sterile preparations are followed fully and consistently.

While this issue of INFUSION focuses on sterile compounding, readers will quickly notice that much of the content can be viewed through a regulatory lens. As they should be, regulators and standards-setting bodies are equally concerned about the public health and safety of patients and health care workers. As our understanding of science and health grows, new evidence continues to shape the best practice recommendations, standards, and regulations that guide our conduct. For example, the many procedures that make up "proper aseptic technique," from hand hygiene to the use of single-dose syringes, evolve over time as new discoveries and events unfold.

In this issue, we review the cadre of policies being issued by the U.S. Food and Drug Administration (FDA) as part of the rulemaking process that stems from passage of the *Drug Quality and Safety Act* (DQSA). We also address new standards from the U.S. Pharmacopeial Convention (USP) regarding the safe handling of hazardous drugs in sterile compounding that will become effective July 1, 2018. And, we've included highlights of a recent NHIA *Talk Infusion* webinar that looked at how compounding pharmacies can prepare for eventual FDA inspections and the challenges that come from the FDA using the improper yardstick of good manufacturing practices (cGMP). We received very positive feedback on this particular webinar and we look forward to continuing to provide members with programs that will bring value to their respective organizations.

Each of these articles points to the shifting ground rules that apply to your practice and the need to stay informed. NHIA's May 22-25, 2017 Annual Conference will address these topics with sessions on sterile compounding, USP <800>, and regulatory updates.

So often the change that must come with compliance prompts a series of examinations. Right now, providers are looking at their lines of business and existing facilities and practices to determine how the cost of infrastructure and operational changes balance against potential revenues associated with preparing therapies that involve hazardous drugs. NHIA remains steadfast in advocating for a clear distinction between infusion providers and outsourcing facilities, throughout the FDA's rulemaking process.

And, just to keep us on our toes, the political winds are beginning to change. With a new administration, priorities and approaches to regulation could be transformed. While it's still too early to tell what that might mean for sterile compounding, it's yet another reason to closely monitor the regulatory process and provide feedback at every opportunity that matters.

When it comes to assuring a positive future amid these challenges, the Association is unwavering in its mission to represent the industry through its advocacy work in Washington, education programs, and member support—to help you and your organization navigate in every way possible through the changing health care landscape. I encourage all NHIA members to educate themselves and participate in the Association-led activities designed to assist you.

As we move forward, our industry must remain accountable for patient safety first. I look forward to working together in this endeavor and to representing your contribution to quality of life for all your patients.

Tyler J. Wilson