



## Office Use Compounding and Your Home Infusion Practice

### Compounding Pharmacy Regulatory Oversight

Since the New England Compounding Center (NECC) tragedy in 2012 that killed 76 patients and injured over 800, there have been several changes in how compounding pharmacy is regulated by state boards of pharmacy and the Food and Drug Administration (FDA). This tragedy led Congress to pass the *Drug Quality and Security Act* (DQSA) in 2013, which altered the regulatory structure for compounding pharmacies. Specifically, the law created a new type of compounding entity called a 503B facility, or outsourcing facility, for the purposes of allowing batch-based, non-patient specific compounding. The more traditional compounding pharmacy (where dispensing occurs pursuant to an individual patient prescription) is considered a 503A pharmacy, or traditional compounder. Both are named after the section of the law that contains the regulatory structure for each type compounder.

There are several differences between these two types of compounding entities including: 1) whether or not the entity has received a prescription for an individual patient, 2) the regulating agency (state board of pharmacy or FDA), and 3) the standards that must be followed during the compounding process. 503A pharmacies must adhere to state board of pharmacy rules which often follow the standards outlined in the United States Pharmacopeia, such as Chapter <797> Pharmaceutical Compounding- Sterile Preparations; while 503B outsourcing facilities must comply with good manufacturing practices (GMPs). Prior to the DQSA, all pharmacy practice, including compounding activities, were regulated at the state level, and the FDA's oversight focused on the manufacture of drug products. Recently, the FDA has taken a more active role with inspecting and regulating both 503A pharmacies and 503B outsourcing facilities.

### Home Infusion and Compounding Pharmacy

In the usual course of providing home infusion services, a pharmacy should not need to dispense/release a compounded product prior to receiving a patient specific prescription. Compliance with section 503A requires compounding a home infusion drug pursuant to a prescription received for an individual patient and dispensing that compounded product directly to the patient. Providing compounded products to a hospital or physician office with or without a prescription, is not considered the practice of home infusion, and as a home infusion provider you should carefully review your practices to ensure you are in compliance with federal and state law. Compounding in anticipation of receiving a patient specific prescription should follow the guidance issued by the FDA in December 2016, titled: [Prescription Requirement Under Section 503A of the Federal Food, Drug, and Cosmetic Act](#). The guidance emphasizes the following rules for compounding pharmacies to follow to ensure their exempt status under 503A is maintained:

- Drugs should be compounded only after receiving the valid individual patient prescription unless the drug is being compounded according to the very limited rules for anticipatory compounding. Additionally, the guidance states that in the instance of anticipatory compounding the compounded product will not be “distributed” until the prescription is received;
- A prescription for a compounded drug product must identify the specific patient for whom the drug is intended; and

- Dispensing of compounded products intended for “office use” is limited to 503B registered facilities.

### **Office Use Compounding**

There is an ongoing debate on Capitol Hill and within the FDA regarding what is commonly termed “office use” compounding. This term itself is loosely defined and is sometimes different from state to state. Generally, the FDA has defined office use compounding as providing a compounded drug without a prescription to another health care provider who will ultimately dispense or administer it to a patient. This practice is not inherent to home infusion pharmacy.

Because office use is not what NHIA would consider a central activity of a home infusion pharmacy, **NHIA has not taken a position on the regulation of office use compounding.** However, since many home infusion referral sources may have knowledge of your compounding abilities, you may on occasion receive requests to fulfill their compounded product needs. In this vein, NHIA cautions that the regulation of these activities has changed in the years since passage of the DQSA. If a pharmacy does engage in this practice, then one should review federal and state laws as this is not considered traditional compounding as it was in the past and may be more appropriately compounded in a 503B outsourcing facility.

### **Conclusion**

NHIA’s primary mission is to ensure the safety of the patients served by our members and feels strongly that patient’s home infusion needs can be met through compliance within the structure of 503A regulations. We highly recommend that NHIA members stay current on how the FDA and states are regulating alternative compounding activities, such as office use, and consider altering your practices to stay in compliance with new regulations.