SAFE ▪ EFFECTIVE ▪ SOLUTIONS

OFA

OUTSOURCING FACILITIES ASSOCIATION

The Outsourcing Facilities Association (OFA) represents registered outsourcing facilities operating under Section 503B of the Federal Food, Drug, and Cosmetic Act, as created by Congress in the Drug Quality and Security Act of 2013 (DQSA).

503B outsourcing facilities fill the gap between large pharmaceutical manufacturers and traditional pharmacies by producing large batches of drugs under the same quality standards as conventional drug manufacturers, for patients and providers whose needs are not met by commercial products. For example, a 503B may manufacture individual unit-dose medications, or versions of an existing drug with a common allergen removed.

Health facilities have widely varying needs for medicines in different forms, doses and concentrations, and they need to have them readily available, especially as the commercial market may not meet those needs. "Outsourcing" originally referred to hospitals relying on outside facilities to provide drug preparations that were not commercially available, rather than expending resources to have in-house hospital pharmacists repackage or compound those drugs on a large scale.

503B outsourcing facilities exist to ensure ready access to safe medications primarily in hospitals, physicians' offices, and other healthcare settings. Particularly with sterile injectable products, where many 503B facilities specialize, 503Bs can often compound and manufacture these products at lower cost and in ready-to-administer forms that providers need.

Congress wrote DQSA in the wake of tragedy. Previously, some pharmacies produced and distributed large batches of drugs without any federal regulation or oversight. Their lax, unregulated practices had tragic results, most notably the New England Compounding Center distributing contaminated steroids that led to 64 patients dying and hundreds more being harmed.

In response to this tragedy, and unregulated activity, Congress passed DQSA. Specifically, Congress in Section 503B created a new type of regulatory entity, outsourcing facilities, to ensure the safety and quality of compounded medicines – those that are specially tailored to meet patient and provider needs that are not met by the commercial market.

503B outsourcing facilities voluntarily register with the Food and Drug Administration, undergo both regular and periodic risk-based inspections, and meet the same robust manufacturing safety and quality standards as commercial drug manufacturers, FDA's Current Good Manufacturing Practices (cGMP). Outsourcing facilities are located only in the United States and every dose from an outsourcing facility is made in America.

The 503B statute also envisions a role for outsourcing facilities in mitigating drug shortages. The law contains flexibilities when products are on FDA's drug shortage list to enable outsourcing facilities to produce medicines that they normally are not permitted to make to help address the drug shortage directly. As the 503B industry has grown and begun to mature in recent years, outsourcing facilities have increasingly sought to fulfill that role to help alleviate drug shortages.

FDA and the health industry increasingly saw and recognized the importance of 503B outsourcing facilities during the COVID-19 pandemic. Throughout the pandemic, the 503B industry stepped up to provide hospitals with hundreds of different formulations and dosage amounts of several lifesaving drugs for COVID patients, facilitated by temporary guidance from FDA. More recently, OFA members have also worked with children's hospitals to help address shortages of liquid albuterol, total parenteral nutrition for preterm infants, and liquid ibuprofen among other essential medicines.