

2.3 – SUMMARY DESCRIPTION OF ENTITIES PAYING THE FEES

As noted, in FY 2015, a total of 64 entities registered as outsourcing facilities. Of these 64 entities, 62 paid the non-small business establishment fee, and 2 paid the small business establishment fee. 9 firms that initially registered as outsourcing facilities in FY 2015 withdrew their registration before the end of the fiscal year. On the last day of FY 2015, 55 firms were registered.

In addition, 2 entities paid a reinspection fee.

Of the 64 firms that were registered as outsourcing facilities at some point during FY 2015, 13 were located in the northeast (e.g., Connecticut, Pennsylvania, New Jersey, New York, and Vermont); 25 in the southeast (e.g., Alabama, Arkansas, Florida, Mississippi, North Carolina, South Carolina, Tennessee, and West Virginia); 6 in the midwest (e.g., Indiana, Kansas, Missouri, and Ohio); 11 in the southwest (e.g., Arizona, Oklahoma, and Texas); 8 in the west (e.g., California, Colorado, Nevada, Utah, and Washington); and 1 foreign firm located in Europe.

Outsourcing facilities vary widely in terms of scope of distribution and the types of products they compound. Some distribute drugs primarily within the state in which they are located pursuant to prescriptions for identified individual patients. Others operate on a larger scale, distributing drug products without prescriptions to healthcare facilities nationwide, and some distribute drugs both with and without prescriptions. For example, one firm may compound and distribute only three drug products while another firm may compound and distribute thousands of different drug products. In addition, one firm may compound five units (e.g., vials or syringes) of a single drug product, while another firm may compound over 100,000 units (e.g., vials or syringes) of a single drug product. Many outsourcing facilities are state-licensed pharmacies, but some are not. In addition, although all outsourcing facilities compound sterile drugs (e.g., injectables for various routes of administration), many also compound non-sterile drugs (e.g., solid oral dosage forms), and most, but not all, outsourcing facilities compound drug products from bulk drug substances. The types of drug products compounded by outsourcing facilities include, for example ophthalmics, anesthetics, antibiotics, hormones, steroids, dermatologic products, and vitamin injections.

Table 3 lists the number of entities that, in FY 2015 (1) registered and remained registered during the FY15, or (2) registered and then de-registered as an outsourcing facility.

TABLE 3: NUMBER OF ENTITIES REGISTERED AND DE-REGISTERED AS OUTSOURCING FACILITIES

Entities	FY 2015
Registered and remained registered through FY 2015	55
Registered for FY 2015 but then de-registered	9