

2.3 – SUMMARY DESCRIPTION OF ENTITIES PAYING THE FEES

As noted, in FY 2016, a total of 68 entities registered as outsourcing facilities. Of these 68 facilities, 62 paid the non-small business establishment fee, and 6 paid the small business establishment fee. Four facilities that were initially registered as outsourcing facilities in FY 2016 withdrew their registration before the end of the fiscal year. On the last day of FY 2016, 64 facilities were registered.

Of the 68 firms that were registered as outsourcing facilities at some point during FY 2016, 12 were located in the northeast (Connecticut, Pennsylvania, New Jersey, New York, and Vermont); 22 in the southeast (Alabama, Arkansas, Florida, Mississippi, North Carolina, South Carolina, and Tennessee); 7 in the midwest (Indiana, Kansas, Missouri, and Ohio); 17 in the southwest (Arizona, Oklahoma, and Texas); and 10 in the west (California, Colorado, Idaho, Nevada, Utah, and Washington).

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 5 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 2016 (1) registered and remained registered during FY 2016, or (2) registered and then de-registered as an outsourcing facility. The total number of registered outsourcing facilities increased from FY 2015 to FY 2016.

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

Entities	FY 2015	FY 2016
Registered and remained registered through the end of the fiscal year	55	64
Registered but then de-registered	9	4