

may purchase autoencoders, adapt existing in-house versions, or use outside contractors. Converting existing terms to MedDRA is estimated to cost from \$20,000 to \$100,000 for drug and biologics firms. Costs are not applicable to blood facilities.

V.D.2.a.iv. *Conversion of legacy safety data.* Some companies reported that they would convert virtually all of their legacy data into MedDRA terms even though it is not required by this proposed rule. Some companies maintain that this conversion includes information from clinical trials. Nonetheless, some companies may not convert their legacy drug safety data into MedDRA or may convert only some of their products, based on criteria associated with experience and history of the drug. ERG estimated that 75 percent of companies would incur conversion costs to allow for the range of company responses. The number of terms that are converted automatically (with autoencoders) or manually will affect conversion costs. Estimated costs per company for converting existing legacy data range from about \$16,500 (for converting 15,000 terms) for very small firms to \$275,000 (for converting roughly 250,000 terms) for very large drug firms. Costs for biologics firms of corresponding size range from \$3,300 (for 3,000 terms) to \$55,000 (for about 50,000 terms). Costs are not applicable to blood facilities.

V.D.2.a.v. *Training of personnel.* Companies reported that staff most likely to receive MedDRA training include medical coders, biostatisticians, and pharmacovigilance, IT, and regulatory affairs personnel. In addition to formal training, medical data coders will require several months of experience before they become

proficient with coding in MedDRA. Training costs are dependent on the number of employees that must be trained in MedDRA and the level of training needed for their relevant duties. Training costs were estimated to range from \$9,300 to \$330,300 for very small to very large drug manufacturers and from \$9,300 to \$90,600 for biologics firms of corresponding size. ERG estimated training costs from \$1,300 to \$4,300 for very small to very large blood facilities.

V.D.2.a.vi. *Revision of standard operating procedures (SOPs).* Companies will revise a substantial group of SOPs in implementing MedDRA. Affected procedures include dictionary/coding, IT, and drug safety/pharmacovigilance. Drug and biologics firms are expected to need from 130 to 1,300 hours for very small to very large firms to revise their SOPs for MedDRA, with costs ranging from \$5,900 to \$59,200. ERG allocated 8 to 50 hours for developing or revising SOPs for blood facilities. Per firm costs for SOPs are estimated to range from \$370 to \$2,260 for very small to very large blood facilities.

V.D.2.b. Recurring costs

V.D.2.b.i. *MedDRA core subscription.* Companies must pay subscription costs on an annual basis to the MedDRA MSSO. Core subscription costs vary with the size of the company and with the level of services. Estimates of costs range from \$5,000 to \$40,000 for drug and biologics firms. ERG judged that blood facilities would incur only modest annual costs associated with MedDRA subscription and updates because of the limited range of terminology describing medical outcomes. ERG assumed that blood

facilities would either work through industry associations to negotiate lower per firm subscription costs or, alternatively, contract with contract research organizations to obtain the necessary MedDRA codes.

V.D.2.b.ii. *MedDRA versions and quarterly updates.* Currently the MSSO intends to provide quarterly updates as well as periodic new versions of MedDRA. Companies did not have a sufficient history with incorporating MedDRA changes to estimate the costs of updates. Cost components would include senior level reviews of each update, communicating the changes to affected personnel, and IT support to upload and reconcile new versions. Costs are estimated to range from \$5,700 to \$43,000 for drug and biologics firms. No costs were assigned to blood facilities.

V.D.2.b.iii. *Maintenance of existing dictionaries.* Companies reported that they may need to maintain their existing dictionaries for an indeterminate time. Conditions that could influence whether and for how long a company would need to maintain its existing dictionaries are: (1) The company uses different dictionaries for its postmarketing safety and clinical study data bases; (2) the company has products in late-stage clinical trials; and (3) the company has marketed products near the end of their useful life. ERG estimates the maintenance costs for existing dictionaries are expected to range from \$4,300 to \$136,400 annually for drug manufacturers and from \$4,300 to \$43,400 annually for biologics manufacturers. No costs were assigned to blood facilities.

Table 18 presents the estimated costs to industry of implementing MedDRA for each cost category.

TABLE 18.—TOTAL COMPLIANCE COSTS OF MEDDRA BY COST CATEGORY

Drugs and biologics	Total cost ¹ (\$ million)	Percent of total ¹
First-Time Costs:		
Planning and coordination	16.3	9
Purchase or development of auto-encoder	20.5	12
Personnel training	46.0	27
Development of IT structure	14.7	9
Legacy safety data conversion	31.9	18
Revision of SOPs	14.8	9
Total First-time	144.2	83
Recurring Costs:		
Annual MedDRA core subscription	6.6	4
MedDRA versioning	6.9	4
Maintenance of additional medical dictionary	15.0	9
Total recurring	28.5	16
Total first year costs (First-time + recurring)	172.8	100

¹ Totals may not add due to rounding.