20.6 – Medwatch Reporting

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The Food and Drug Administration (FDA) is responsible for protecting the public health by assuring the safety, efficacy, and security of marketed medical products, such as drugs and medical devices (including OTCs and dietary supplements). In order to perform ongoing safety surveillance of medical products, the FDA relies on the voluntary reporting of serious adverse events, product quality problems and product use errors. FDA MedWatch enables healthcare professionals and consumers to report serious problems that they suspect are associated with the drugs and medical devices they prescribe, dispense, or use. Healthcare professionals and consumers may report adverse events and product problems to MedWatch by calling 1800-FDA-1088, by submitting the MedWatch 3500 form by mail or fax, or by going online to the FDA Web page. CMS encourages Part D sponsors to educate prescribers and pharmacy providers about the importance of reporting adverse events, product problems and product use errors, as well as how to utilize the FDA Medwatch reporting mechanisms. A broader discussion on Medwatch reporting, including downloadable Medwatch forms, is available at the FDA MedWatch Web page (see Appendix A).