

Subpart C—User Facility Reporting Requirements

- 803.30 Individual adverse event reports; user facilities.
 803.32 Individual adverse event report data elements.
 803.33 Semiannual reports.

Subpart D—[Reserved]**Subpart E—Manufacturer Reporting Requirements**

- 803.50 Individual adverse event reports; manufacturers.
 803.52 Individual adverse event report data elements.
 803.53 Five-day reports.
 803.55 Baseline reports.
 803.56 Supplemental reports.
 803.57 Annual certification.
 803.58 Foreign manufacturers.

Authority: Secs. 502, 510, 519, 520, 701, 704 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352, 360, 360i, 360j, 371, 374).

Subpart A—General Provisions**§ 803.1 Scope.**

(a) This part establishes requirements for medical device reporting. Under this part, device user facilities and manufacturers must report deaths and serious injuries to which a device has or may have caused or contributed, and must establish and maintain adverse event files. Manufacturers are also required to report certain device malfunctions and submit an annual report to FDA certifying that the correct number of medical device reports were filed during the previous 12-month period or, alternatively, that no reports were required during that same time period. These reports will assist FDA in protecting the public health by helping to ensure that devices are not adulterated or misbranded and are safe and effective for their intended use.

(b) This part supplements and does not supersede other provisions of this subchapter, including the provisions of part 820 of this chapter.

(c) References in this part to regulatory sections of the Code of Federal Regulations are to Chapter I of title 21, unless otherwise noted.

§ 803.3 Definitions.

(a) *Act* means the Federal Food, Drug, and Cosmetic Act.

(b) *Ambulatory surgical facility (ASF)* means a distinct entity that operates for the primary purpose of furnishing same day outpatient surgical services to patients. An ASF may be either an independent entity (i.e., not a part of a provider of services or any other facility) or operated by another medical entity (e.g., under the common ownership, licensure or control of an entity). An ASF is subject to this regulation regardless of whether it is

licensed by a Federal, State, municipal, or local government or regardless of whether it is accredited by a recognized accreditation organization. If an adverse event meets the criteria for reporting, the ASF must report that event regardless of the nature or location of the medical service provided by the ASF.

(c) *Become aware* means that an employee of the entity required to report has acquired information reasonably suggesting a reportable adverse event has occurred. Device user facilities are considered to have “become aware” when medical personnel, as defined in paragraph (r) of this section, who are employed by or otherwise formally affiliated with the facility, acquire such information about a reportable event. Manufacturers are considered to have “become aware” of an event when:

(1) Any employee becomes aware of a reportable event that is required to be reported within 30 days, or that is required to be reported within 5 days pursuant to a written request from FDA under 803.53(b); and

(2) Any employee, who is a person with management or supervisory responsibilities over persons with regulatory, scientific, or technical responsibilities, or a person whose duties relate to the collection and reporting of adverse events, becomes aware that a reportable MDR event or events, from any information, including any trend analysis, necessitate remedial action to prevent an unreasonable risk of substantial harm to the public health.

(d) *Caused or contributed* means that a death or serious injury was or may have been attributed to a medical device, or that a medical device was or may have been a factor in a death or serious injury, including events occurring as a result of:

- (1) Failure;
- (2) Malfunction;
- (3) Improper or inadequate design;
- (4) Manufacture;
- (5) Labeling; or
- (6) User error.

(e) (1) *Device family* means a group of one or more devices manufactured by or for the same manufacturer and having the same:

- (i) Basic design and performance characteristics related to device safety and effectiveness,
- (ii) Intended use and function, and
- (iii) Device classification and product code.

(2) Devices that differ only in minor ways not related to safety or effectiveness can be considered to be in the same device family. Factors such as brand name and common name of the device and whether the devices were

introduced into commercial distribution under the same 510(k) or premarket approval application (PMA), may be considered in grouping products into device families.

(f) *Device user facility* means a hospital, ambulatory surgical facility, nursing home, outpatient diagnostic facility, or outpatient treatment facility as defined in paragraphs (l), (b), (s), (t), and (u), respectively, of this section, which is not a “physician’s office,” as defined in paragraph (w) of this section. School nurse offices and employee health units are not device user facilities.

(g) [Reserved]

(h) [Reserved]

(i) *Expected life of a device* (required on the manufacturer’s baseline report) means the time that a device is expected to remain functional after it is placed into use. Certain implanted devices have specified “end of life” (EOL) dates. Other devices are not labeled as to their respective EOL, but are expected to remain operational through maintenance, repair, upgrades, etc., for an estimated period of time.

(j) *FDA* means the Food and Drug Administration.

(k) *Five-day report* means a medical device report that must be submitted by a manufacturer to FDA pursuant to § 803.53, on FDA Form 3500A or electronic equivalent as approved under § 803.14, within 5 work days.

(l) *Hospital* means a distinct entity that operates for the primary purpose of providing diagnostic, therapeutic (medical, occupational, speech, physical, etc.), surgical and other patient services for specific and general medical conditions. Hospitals include general, chronic disease, rehabilitative, psychiatric, and other special-purpose facilities. A hospital may be either independent (e.g., not a part of a provider of services or any other facility) or may be operated by another medical entity (e.g., under the common ownership, licensure or control of another entity). A hospital is covered by this regulation regardless of whether it is licensed by a Federal, State, municipal or local government or whether it is accredited by a recognized accreditation organization. If an adverse event meets the criteria for reporting, the hospital must report that event regardless of the nature or location of the medical service provided by the hospital.

(m) *Malfunction* means the failure of a device to meet its performance specifications or otherwise perform as intended. Performance specifications include all claims made in the labeling for the device. The intended