Subpart D—Importer Reporting Requirements

§ 803.40 If I am an importer, what kinds of individual adverse event reports must I submit, when must I submit them, and to whom must I submit them?

§ 803.42 If I am an importer, what information must I submit in my individual adverse event reports?

Subpart E—Manufacturer Reporting Requirements

§ 803.50 If I am a manufacturer, what reporting requirements apply to me?

§ 803.52 If I am a manufacturer, what information must I submit in my individual adverse event reports?

§ 803.53 If I am a manufacturer, in which circumstances must I submit a 5-day report?

§ 803.56 If I am a manufacturer, in what circumstances must I submit a supplemental or followup report and what are the requirements for such reports?

§ 803.58 Foreign manufacturers.


Source: 70 FR 9519, July 13, 2005, unless otherwise noted.

Subpart A—General Provisions

§ 803.1 What does this part cover?

(a) This part establishes the requirements for medical device reporting for device user facilities, manufacturers, importers, and distributors. If you are a device user facility, you must report deaths and serious injuries that your device has or may have caused or contributed to, establish and maintain adverse event files, and submit summary annual reports. If you are a manufacturer or importer, you must report deaths and serious injuries that your device has or may have caused or contributed to, you must report certain device malfunctions, and you must establish and maintain adverse event files. If you are a manufacturer, you must also submit specified followup. These reports help us to protect the public health by helping to ensure that devices are not adulterated or misbranded and are safe and effective for their intended use. If you are a medical device distributor, you must maintain records (files) of incidents, but you are not required to report these incidents.

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

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is required to be reported within 30 calendar days or that is required to be reported within 5 work days because we had requested reports in accordance with §803.53(b). You are also considered to have become aware of an event when any of your employees with management or supervisory responsibilities over persons with regulatory, scientific, or technical responsibilities, or whose duties relate to the collection and reporting of adverse events, becomes aware, from any information, including any trend analysis, that a reportable MDR event or events necessitates remedial action to prevent an unreasonable risk of substantial harm to the public health.

(3) If you are an importer, you are considered to have become aware of an event when any of your employees becomes aware of a reportable event that is required to be reported by you within 30 days.

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.

Device user facility means a hospital, ambulatory surgical facility, nursing home, outpatient diagnostic facility, or outpatient treatment facility as defined in this section, which is not a physician’s office, as defined in this section. School nurse offices and employee health units are not device user facilities.

Distributor means any person (other than the manufacturer or importer) who furthers the marketing of a device from the original place of manufacture to the person who makes final delivery or sale to the ultimate user, but who does not repackage or otherwise change the container, wrapper, or labeling of the device or device package. If you repackage or otherwise change the container, wrapper, or labeling, you are considered a manufacturer as defined in this section.

Expected life of a device 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 activities such as maintenance, repairs, or upgrades, for an estimated period of time.

FDA, we, or us means the Food and Drug Administration.

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

Hospital means a distinct entity that operates for the primary purpose of providing diagnostic, therapeutic (such as medical, occupational, speech, physical), 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.

Importer means any person who imports a device into the United States and who furthers the marketing of a device from the original place of manufacture to the person who makes final delivery or sale to the ultimate user, but who does not repackage or otherwise change the container, wrapper, or labeling of the device or device package. If you repackage or otherwise change the container, wrapper, or labeling, you are considered a manufacturer as defined in this section.
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 performance of a device refers to the intended use for which the device is labeled or marketed, as defined in §801.4 of this chapter.

Manufacturer means any person who manufactures, prepares, propagates, compounds, assembles, or processes a device by chemical, physical, biological, or other procedure. The term includes any person who either:

1. Repackages or otherwise changes the container, wrapper, or labeling of a device in furtherance of the distribution of the device from the original place of manufacture;
2. Initiates specifications for devices that are manufactured by a second party for subsequent distribution by the person initiating the specifications;
3. Manufactures components or accessories that are devices that are ready to be used and are intended to be commercially distributed and intended to be used as is, or are processed by a licensed practitioner or other qualified person to meet the needs of a particular patient; or
4. Is the U.S. agent of a foreign manufacturer.

Manufacturer or importer report number. Manufacturer or importer report number means the number that uniquely identifies each individual adverse event report submitted by a manufacturer or importer. This number consists of the following three parts:

1. The FDA registration number for the manufacturing site of the reported device, or the registration number for the importer. If the manufacturing site or the importer does not have an establishment registration number, we will assign a temporary MDR reporting number until the site is registered in accordance with part 807 of this chapter. We will inform the manufacturer or importer of the temporary MDR reporting number;
2. The four-digit calendar year in which the report is submitted; and
3. The five-digit sequence number of the reports submitted during the year, starting with 00001. (For example, the complete number will appear as follows: 1234567–1995–00001.)

MDR means medical device report.

MDR reportable event (or reportable event) means:

1. An event that user facilities become aware of that reasonably suggests that a device has or may have caused or contributed to a death or serious injury; or
2. An event that manufacturers or importers become aware of that reasonably suggests that one of their marketed devices:
   (i) May have caused or contributed to a death or serious injury, or
   (ii) Has malfunctioned and that the device or a similar device marketed by the manufacturer or importer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

Medical personnel means an individual who:

1. Is licensed, registered, or certified by a State, territory, or other governing body, to administer health care;
2. Has received a diploma or a degree in a professional or scientific discipline;
3. Is an employee responsible for receiving medical complaints or adverse event reports; or
4. Is a supervisor of these persons.

Nursing home means:

1. An independent entity (i.e., not a part of a provider of services or any other facility) or one operated by another medical entity (e.g., under the common ownership, licensure, or control of an entity) that operates for the primary purpose of providing:
   (i) Skilled nursing care and related services for persons who require medical or nursing care;
   (ii) Hospice care to the terminally ill; or
   (iii) Services for the rehabilitation of the injured, disabled, or sick.
2. A nursing home is subject to 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 nursing home must report that event regardless of the nature or location of
the medical service provided by the nursing home.

**Outpatient diagnostic facility.** (1) Outpatient diagnostic facility means a distinct entity that:

(i) Operates for the primary purpose of conducting medical diagnostic tests on patients,

(ii) Does not assume ongoing responsibility for patient care, and

(iii) Provides its services for use by other medical personnel.

(2) Outpatient diagnostic facilities include outpatient facilities providing radiography, mammography, ultrasonography, electrocardiography, magnetic resonance imaging, computerized axial tomography, and in vitro testing. An outpatient diagnostic facility may be either independent (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 outpatient diagnostic facility 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 outpatient treatment facility must report that event regardless of the nature or location of the medical service provided by the outpatient treatment facility.

**Patient of the facility** means any individual who is being diagnosed or treated and/or receiving medical care at or under the control or authority of the facility. This includes employees of the facility or individuals affiliated with the facility who, in the course of their duties, suffer a device-related death or serious injury that has or may have been caused or contributed to by a device used at the facility.

**Physician’s office** means a facility that operates as the office of a physician or other health care professional for the primary purpose of examination, evaluation, and treatment or referral of patients. Examples of physician offices include dentist offices, chiropractor offices, optometrist offices, nurse practitioner offices, school nurse offices, school clinics, employee health clinics, or freestanding care units. A physician’s office may be independent, a group practice, or part of a Health Maintenance Organization.

**Remedial action** means any action other than routine maintenance or servicing of a device where such action is necessary to prevent recurrence of a reportable event.

**Serious injury** means an injury or illness that:

(1) Is life-threatening,

(2) Results in permanent impairment of a body function or permanent damage to a body structure, or

(3) Necessitates medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure.

**Permanent** means irreversible impairment or damage to a body structure or function, excluding trivial impairment or damage.

**User facility report number** means the number that uniquely identifies each report submitted by a user facility to
Food and Drug Administration, HHS

§ 803.10 Generally, what are the reporting requirements that apply to me?

(a) If you are a device user facility, you must submit reports (described in subpart C of this part), as follows:
   (1) Submit reports of individual adverse events no later than 10 work days after the day that you become aware of a reportable event:
      (i) Submit reports of device-related deaths to us and to the manufacturer, if known; or
      (ii) Submit reports of device-related serious injuries to the manufacturers or, if the manufacturer is unknown, submit reports to us.
   (2) Submit annual reports (described in § 803.33) to us.

(b) If you are an importer, you must submit reports (described in subpart D of this part), as follows:
   (1) Submit reports of individual adverse events no later than 30 calendar days after the day that you become aware of a reportable event:
      (i) Submit reports of device-related deaths or serious injuries to us and to the manufacturer; or
      (ii) Submit reports of device-related malfunctions to the manufacturer.
   (2) [Reserved]