

(a) Training and education programs informing employees about obligations under this section, including how to identify and report MDR reportable events;

(b) Internal systems that provide for timely and effective identification, communication, and evaluation of events that may be subject to MDR requirements, a standardized review process/procedure for determining when an event meets the criteria for reporting under this part, and timely transmission of complete MDR's to FDA and/or manufacturers; and

(c) Documentation and recordkeeping requirements for:

(1) Information that may be the subject of an MDR;

(2) All MDR's and information submitted to FDA and manufacturers;

(3) Information that facilitates the submission of certification reports; and

(4) Systems that ensure access to information that facilitates timely followup and inspection by FDA.

§ 804.35 Files.

(a) A device distributor shall establish a device complaint file in accordance with § 820.198 of this chapter and maintain a record of any information, including any written or oral communication, received by the distributor concerning all events that were considered for possible reporting under this part. Device incident records shall be prominently identified as such and shall be filed by device. The file shall also contain a copy of any MDR along with any additional information submitted to FDA under this part. A distributor shall maintain records that document the submission of copies of MDR's to manufacturers.

(b) A device distributor shall retain copies of the records required to be maintained under this section for a period of 2 years from the date that the report or additional information is submitted to FDA under § 804.25, or for a period of time equivalent to the design and expected life of the device, whichever is greater, even if the distributor has ceased to distribute the device that is the subject of the report or the additional information.

(c) A device distributor shall maintain the device complaint files estab-

lished under this section at the distributor's principal business establishment. A distributor that is also a manufacturer may maintain the file at the same location as the manufacturer maintains its complaint file under §§ 820.180 and 820.198 of this chapter. A device distributor shall permit any authorized FDA employee, during all reasonable times, to have access to, and to copy and verify, the records required by this part.

PART 805—CARDIAC PACEMAKER REGISTRY

Subpart A—General Provisions

Sec.

805.1 Scope.

805.3 Definitions.

Subpart B—Submission of Information

805.10 Submission of information by physicians and providers.

805.20 How to submit information.

805.25 Confidentiality.

AUTHORITY: 42 U.S.C. 1395y(h), 1395y note.

SOURCE: 52 FR 27763, July 23, 1987, unless otherwise noted.

Subpart A—General Provisions

§ 805.1 Scope.

(a) This part provides for a nationwide cardiac pacemaker registry and requires any physician and any provider of services who requests or receives payment from Medicare for the implantation, removal, or replacement of permanent cardiac pacemakers and pacemaker leads to submit certain information to the registry. If the physician or the provider of services does not submit the information according to this part and 42 CFR 409.19(a) and 410.64(a), HCFA, which administers the Medicare program, will deny payment to the physician or the provider. FDA will use the information submitted to the registry to track the performance of permanent pacemakers and pacemaker leads and to perform studies and analyses regarding the use of the devices, and to transmit data to HCFA to assist HCFA in administering the Medicare program and to other Department of Health and Human Services'

components to carry out statutory responsibilities.

(b) Information submitted to the registry by a physician or a provider of services (and any release by FDA or HCFA of that information) does not necessarily reflect a conclusion by the submitter, FDA, or HCFA that the information constitutes an admission that a pacemaker device or lead failed to operate within its performance specifications. A submitter need not admit, and may deny, that the information submitted to the registry constitutes an admission that the pacemaker device or lead failed to operate within its performance specifications.

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

§805.3 Definitions.

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

(b) *HCFA* means the Health Care Financing Administration.

(c) A *pacemaker* or *pacemaker device* is a device that produces periodic electrical impulses to stimulate the heart. It consists of two basic components: a pulse generator and one or more leads. See §870.3610 for a more detailed definition.

(d) A *pacemaker lead* is a flexible, insulated wire connected at one end to a pacemaker's pulse generator and at the other end to the heart. It transmits electrical stimuli to and from the heart. See §870.3680(b) for a more detailed definition.

(e) A *physician* is a doctor of medicine or osteopathy legally authorized to practice medicine and surgery by applicable laws of the State in which he or she performs such function or actions. (This definition includes an osteopathic practitioner.)

(f) A *PRO* is a Utilization and Quality Control Peer Review Organization that contracts with the Secretary of Health and Human Services to review health care services funded by the Medicare program to determine whether those services are reasonable, medically necessary, furnished in the appropriate setting, and are of a quality which meets professionally recognized standards.

(g) A *provider* is a hospital, skilled nursing facility, comprehensive outpatient rehabilitation facility, home health agency, or a hospice that has in effect an agreement to participate in Medicare.

(h) A *warranty* is an express or implied guarantee, under contract or State law, of the integrity of a pacemaker device or pacemaker lead and of the manufacturer's responsibility for the repair or replacement of defective parts of a pacemaker device or pacemaker lead.

(i) Any terms defined in section 201 of the Federal Food, Drug, and Cosmetic Act will have that definition.

Subpart B—Submission of Information

§805.10 Submission of information by physicians and providers.

A physician or a provider of services that requests or receives payment from Medicare for the implantation, removal, or replacement of a permanent cardiac pacemaker device or pacemaker lead shall submit the following information on a specified form to HCFA for inclusion in the pacemaker registry provided for by FDA under §805.1:

- (a) Provider number.
- (b) Patient's health insurance claim number (HICN).
- (c) Patient's name.
- (d) Date of the procedure.
- (e) Identification number (used by PRO's) and name of the physician who ordered the procedure.
- (f) Identification number (used by PRO's) and name of the operating physician.
- (g) For each device (pulse generator, atrial lead, ventricular lead) implanted during the procedure about which the report is being made: the name of the manufacturer, model number, serial number, and the warranty expiration date.

(h) For each device (pulse generator, atrial lead, ventricular lead) removed or replaced during the procedure about which the report is being made: the name of the manufacturer; model number; serial number; the warranty expiration date, if known; the date the device was initially implanted, if known;

whether a device that was replaced was left in the body; if the device was not left in the body, whether it was returned to the manufacturer.

(Information collection requirements approved by the Office of Management and Budget under control number 0910-0234)

§ 805.20 How to submit information.

Information shall be submitted to the registry in the form and manner required under general instructions of the Medicare program (see 42 CFR 409.19(a) and 410.64(a)).

§ 805.25 Confidentiality.

(a) FDA and HCFA will keep confidential, and will not reveal to the public, any specific information that identifies by name a recipient of any pacemaker device or lead or that would otherwise identify a specific recipient.

(b) Public disclosure of all other information under this part will be governed by the Freedom of Information Act (5 U.S.C. 552), the Privacy Act of 1974 (5 U.S.C. 552a), the Department of Health and Human Services' public information regulations (45 CFR part 5), FDA's public information regulations (21 CFR part 20), and HCFA's public information regulations (subpart B of 42 CFR part 401).

PART 806—MEDICAL DEVICES; REPORTS OF CORRECTIONS AND REMOVALS

Subpart A—General Provisions

Sec.

806.1 Scope.

806.2 Definitions.

Subpart B—Reports and Records

806.10 Reports of corrections and removals.

806.20 Records of corrections and removals not required to be reported.

806.30 FDA access to records.

806.40 Public availability of reports.

AUTHORITY: 21 U.S.C. 352, 360, 360i, 360j, 371, 374.

SOURCE: 62 FR 27191, May 19, 1997, unless otherwise noted.

Subpart A—General Provisions

§ 806.1 Scope.

(a) This part implements the provisions of section 519(f) of the Federal Food, Drug, and Cosmetic Act (the act) requiring device manufacturers and importers to report promptly to the Food and Drug Administration (FDA) certain actions concerning device corrections and removals, and to maintain records of all corrections and removals regardless of whether such corrections and removals are required to be reported to FDA.

(b) The following actions are exempt from the reporting requirements of this part:

(1) Actions taken by device manufacturers or importers to improve the performance or quality of a device but that do not reduce a risk to health posed by the device or remedy a violation of the act caused by the device.

(2) Market withdrawals as defined in § 806.2(h).

(3) Routine servicing as defined in § 806.2(k).

(4) Stock recoveries as defined in § 806.2(l).

[62 FR 27191, May 19, 1997, as amended at 63 FR 42232, Aug. 7, 1998]

§ 806.2 Definitions.

As used in this part:

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

(b) *Agency* or *FDA* means the Food and Drug Administration.

(c) *Consignee* means any person or firm that has received, purchased, or used a device subject to correction or removal.

(d) *Correction* means the repair, modification, adjustment, relabeling, destruction, or inspection (including patient monitoring) of a device without its physical removal from its point of use to some other location.

(e) *Correction or removal report number* means the number that uniquely identifies each report submitted.

(f) *Importer* means, for the purposes of this part, any person who imports a device into the United States.