

each of whom will sign a certification statement pertaining to their respective identified organizational component(s) or site(s), provided that all organizational components and sites are covered under a certification statement.

(c) The report shall contain the following information:

(1) Name, address, and FDA registration number or FDA assigned identification number of the firm;

(2) Name, title, address, telephone number, signature, and date of signature of the person making the certification;

(3) Name, address, and FDA registration number or FDA assigned identification number for the distributor covered by the certification, and the number of reports submitted for devices distributed by the distributor;

(4) A statement certifying that:

(i) The individual certifying for the firm has read the MDR requirements under part 804;

(ii) The firm has established a system to implement MDR reporting;

(iii) Following the procedures of its MDR reporting system, the firm submitted the specified number of reports, or no reports, during the certification period; and

(iv) The certification is made to the best of the certifying official's knowledge and belief.

[62 FR 13306, Mar. 20, 1997]

**§ 804.31 Additional requirements.**

Requests for additional information. If FDA determines that the protection of the public health requires information in addition to that included in the medical device reports submitted to FDA under this part, the distributor shall, upon FDA's request, submit such additional information. Any request by FDA under this section shall state the reason or purpose for which the information is being requested, and specify a due date for the submission of such information.

**§ 804.32 Supplemental information.**

(a) Only one MDR is required under this part if the distributor becomes aware, from more than one source, of information concerning the same patient and the same event.

(b) An MDR that would otherwise be required under this section is not required by the distributor if:

(1) The distributor determines that the information received is erroneous in that a death, serious injury, serious illness, or the malfunction did not occur; or

(2) The distributor determines that the information received is erroneous in that the device that is the subject of the information was distributed by another distributor. A distributor shall forward to FDA any report that is erroneously sent to the distributor, with a cover letter explaining that the product in question is not distributed by that firm.

(c) A report or information submitted by a distributor under this part (and any release by FDA of that report or information) does not necessarily reflect a conclusion by the party submitting the report or by FDA that the report or information constitutes an admission that the device, the establishment submitting the report, or employees thereof, caused or contributed to a death, serious injury, serious illness, or malfunction. A distributor need not admit, and may deny, that the report or information submitted under this part constitutes an admission that the device, the party submitting the report, or employees thereof, caused or contributed to a death or serious injury, serious illness, or malfunction.

**§ 804.33 Alternative reporting requirements.**

(a) Distributors may request exemptions from any or all of the reporting requirements in this part. These requests are required to be in writing and to include both the information necessary to identify the firm and device and an explanation why the request is justified.

(b) FDA may grant a distributor, in writing, an exemption from any or all of the reporting requirements in this part and may change the frequency of reporting to quarterly, semiannually, annually, or other appropriate time periods. In granting such exemptions, FDA may impose other reporting requirements to ensure the protection of public health and safety. FDA may also

authorize the use of alternative reporting media such as magnetic tape or disk, in lieu of FDA forms.

(c) FDA may revoke alternative reporting options, in writing, if FDA determines that protection of the public health justifies a return to the requirements as stated in this part.

#### § 804.34 Written MDR procedures.

Device distributors shall maintain and implement written MDR procedures in the following areas:

(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 follow-up 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 established 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

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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