CAREIER

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The U.S. federal regulations mandate device manufacturers of specified medical devices adopt a tracking system for the purpose of facilitating communications to providers and patients in the event the device has significant problems or presents a serious health risk.

- The tracking system must provide the current location for tracked devices within 3 to 10 business days, including those devices which have been implanted in patients.
- Manufacturers bear the responsibility of establishing a written standard operating procedure which includes (a) the method for tracking the device (i.) throughout the distribution process and (ii.) for the life of the device and (b) a quality assurance program which includes auditing procedures.
- The list of devices requiring tracking changes regularly as devices are added or removed.

At present, the Food and Drug Administration (FDA) has issued tracking orders for 48 product codes, equating roughly to 14,500 unique devices. These devices are typically class II or class III devices intended to be implanted in the human body for more than a year, intended to be used outside a device user facility and are life-sustaining or life-supporting, or which would be reasonably likely to have serious adverse health consequences upon failure. However, the FDA may, at its discretion, issue tracking orders for a "new" device as part of the premarket clearance process.

CAREier offers a fully automated, cost-effective tracking system solution which:

- ✓gathers and verifies updated end-user (patient) information multiple times a year
- ✓directly connects device manufacturers to healthcare providers, patients and the FDA
- ✓fully complies with changing federal regulations
- ✓monitors the changing tracked-devices list updated by the FDA

Contact CAREier today to find out how you can be assured of world-class communication to patients and providers while increasing revenue and lowering costs.

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Frequently Asked Questions

How do I know if my device must be tracked?

The FDA will issue a tracking order directly to the manufacturer for devices which must be tracked.

How long do I need to track my devices?

Tracking requirements, related to tracking orders, continue for the useful life of the device until:

- the FDA notifies the manufacturer, in writing, that a device is released from tracking requirements; or
- the manufacturer has evidence to confirm the device has been (a) returned, destroyed, or explanted or (b) the patient has died.

Also note: Refurbish and remanufacturers of tracked devices that remain in domestic commercial distribution are also subject to tracking requirements and should be able to ensure the original manufacturer can promptly locate the devices.

Devices with an approved Premarket Approval Application (PMA) and a tracking order may, at the sponsor's request or by the FDA's initiative, have the need for continued tracking reassessed 10 years from the date of the original PMA's approval.

Am I still responsible for tracking if a patient declines tracking?

- Regulations require manufacturers establish a written standard operating procedure (SOP) for the collection, maintenance and auditing of the data specified for tracking in Title 21 CFR 821.25. The SOP should include the following:
  - o Your data collection and recording procedures, including explanations of when and why required data could not be collected.
  - o Recording all modifications or changes to your tracking system or the data collected/maintained, including dates and reasons for modification/changes.
  - o A quality assurance program including a statistically relevant audit at no less than 6-month intervals for the first 3 years of distribution and at least once a year thereafter.
- You are required to keep current records in accordance with your SOPs if the device is in use or distribution, whether the tracked device is still being manufactured or is being distributed.

What do I do if a distributor, final distributor, or a multiple distributor of my device fails to comply with their tracking obligations in Title 21 CFR 821.30?

You are required to notify your local FDA district office, as required by Title 21 CFR 821.25(d).

My device is not listed in the "ProCode" list, but the FDA is requiring a post-market surveillance. How long must I conduct surveillance on my devices?

The length of surveillance will depend on the post-market surveillance period specified in the FDA's order. Periods longer than 36 months require your agreement. If the FDA believes it important to track a device for longer than 36 months and you do not agree, the Medical Devices Dispute Resolution Panel will be used to resolve the matter.

What are my requirements towards tracking if I stop distributing a tracked device, and stay in business?

If you stop distributing tracked devices but stay in business, you are still responsible to track the previously distributed devices.

What are my requirements if someone else buys my business?

If you are acquired by another entity, and they now have the right to manufacture or distribute the tracked devices, the new entity is required to continuing the tracking responsibilities.

What are my requirements if I go out of business and no one takes ownership of my manufacturing rights?

You are required to notify the FDA at the same time you provide notification of the business closure to any government agency, court, or supplier. In addition to notifying the FDA, you must provide the FDA with a complete set of tracking records and information.

What information should my tracking system contain?

The required information is identified in Title 21 CFR 821.25 which is attached to the end of this document.

Can I contract out management of my tracking program?

Yes! Manufacturers, however, remain responsible for making sure programs comply with the tracking requirements. You cannot alter, change, or in any way avoid tracking obligations unless the FDA approves your written request for a variance or an exemption.

Will the FDA review my tracking program during inspections?

Tracking systems are subject to FDA inspection.

What type of auditing do I need to perform on my tracking program?

You must ensure your tracking system works. Also, you are required to maintain a quality assurance program and perform audits at 6-month intervals for the first 3 years after receiving a tracking order, then annually after. Audits should verify the tracking method works and the information collected is accurate so that, in the event of a recall, the right persons are notified in a timely fashion.

What must my tracking method do?

- Tracking methods must provide certain critical information about the location of a tracked device within a short time frame. This includes both implanted and nonimplanted devices. You have 3 working days to provide critical information about devices that have not yet been distributed to a patient and 10 working days for devices that have been distributed to patients.
    - o For non-implanted devices – You must provide the name, address and telephone number of the distributor, multiple distributors, or final distributor holding the device for distribution and the location of the device.
    - o For Implanted devices – You must provide the lot number, batch number, model number, or serial number of the tracked device or other identifier necessary to provide for effective tracking of the device; the date you shipped the device; the name, mailing address, and telephone number of the prescribing and/or implanting physician; the name, mailing address, and telephone number of the physician regularly following the patient if different than the prescribing or implanting physician; If applicable, the date your device was explanted and the name, mailing address, and telephone number of the explanting physician; the date of the patient's death; or the date the device was returned and permanently retired from use, or otherwise permanently disposed of.

[Code of Federal Regulations]
[Title 21, Volume 8]
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TITLE 21 – FOOD AND DRUGS
CHAPTER 1 – FOODANDDRUGADMINISTRATION, DEPT. OF HEALTH AND HUMAN SERVICES
SUBCHAPTER H – MEDICAL DEVICES
PART 821 – MEDICAL DEVICE TRACKING REQUIREMENTS
Subpart B – TRACKING REQUIREMENTS

§821.25 Device tracking system and content requirements: manufacturer requirements.

(a) A manufacturer of a tracked device shall adopt a method of tracking for each such type of device that it distributes that enables a manufacturer to provide FDA with the following information in writing for each tracked device distributed:

(1) Except as required by order under section 518(e) of the act, within 3 working days of a request from FDA, prior to the distribution of a tracked device to a patient, the name, address, and telephone number of the distributor, multiple distributor, or final distributor holding the device for distribution and the location of the device;

(2) Within 10 working days of a request from FDA for tracked devices that are intended for use by a single patient over the life of the device, after distribution to or implantation in a patient:

(i) The unique device identifier (UDI), lot number, batch number, model number, or serial number of the device or other identifier necessary to provide for effective tracking of the devices;

(ii) The date the device was shipped by the manufacturer;

(iii) The name, address, telephone number, and social security number (if available) of the patient receiving the device, unless not released by the patient under 821.SS(a);

(iv) The date the device was provided to the patient;

(v) The name, mailing address, and telephone number of the prescribing physician;

(vi) The name, mailing address, and telephone number of the physician regularly following the patient if different than the prescribing physician; and

(vii) If applicable, the date the device was explanted and the name, mailing address, and telephone number of the explanting physician; the date of the patient's death; or the date the device was returned to the manufacturer, permanently retired from use, or otherwise permanently disposed of.

(3) Except as required by order under section 518(e) of the act, within 10 working days of a request from FDA for tracked devices that are intended for use by more than one patient, after the distribution of the device to the multiple distributor:

(i) The unique device identifier (UDI), lot number, batch number, model number, or serial number of the device or other identifier necessary to provide for effective tracking of the devices;

(ii) The date the device was shipped by the manufacturer;

(iii) The name, address, and telephone number of the multiple distributor;

(iv) The name, address, telephone number, and social security number (if available) of the patient using the device, unless not released by the patient under 821.55(a);

(v) The location of the device;

(vi) The date the device was provided for use by the patient;

(vii) The name, address, and telephone number of the prescribing physician; and

(viii) If and when applicable, the date the device was returned to the manufacturer, permanently retired from use, or otherwise permanently disposed of.

(b) A manufacturer of a tracked device shall keep current records in accordance with its standard operating procedure of the information identified in paragraphs (a)(1), (a)(2) and (a)(3)(i) through (a)(3)(iii) of this section on each tracked device released for distribution for as long as such device is in use or in distribution for use.

(c) A manufacturer of a tracked device shall establish a written standard operating procedure for the collection, maintenance, and auditing of the data specified in paragraphs (a) and (b) of this section. A manufacturer shall make this standard operating procedure available to FDA upon request. A manufacturer shall incorporate the following into the standard operating procedure:

(1) Data collection and recording procedures, which shall include a procedure for recording when data which is required under this part is missing and could not be collected and the reason why such required data is missing and could not be collected;

(2) A method for recording all modifications or changes to the tracking system or to the data collected and maintained under the tracking system, reasons for any modification or change, and dates of any modification or change. Modification and changes included under this requirement include modifications to the data (including termination of tracking), the data format, the recording system, and the file maintenance procedures system; and

(3) A quality assurance program that includes an audit procedure to be run for each device product subject to tracking, at not less than 6-month intervals for the first 3 years of distribution and at least once a year thereafter. This audit procedure shall provide for statistically relevant sampling of the data collected to ensure the accuracy of data and performance testing of the functioning of the tracking system.

(d) When a manufacturer becomes aware that a distributor, final distributor, or multiple distributor has not collected, maintained, or furnished any record or information required by this part, the manufacturer shall notify the FDA district office responsible for the area in which the distributor, final distributor, or multiple distributor is located of the failure of such persons to comply with the requirements of this part. Manufacturers shall have taken reasonable steps to obtain compliance by the distributor, multiple distributor, or final distributor in question before notifying FDA.

(e) A manufacturer may petition for an exemption or variance from one or more requirements of this part according to the procedures in 821.2 of this chapter.

(58 FR 43447, Aug. 16, 1993, as amended at 67 FR 5951, Feb. 8, 2002; 78 FR 58822, Sept. 24, 2013]