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Modernizing Hospital Adverse Event Reporting

14 December 2016

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Firm Overview

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- More than 1,500 lawyers in 46 offices across 21 countries
- We also have strong working relationships with independent firms in Europe and Latin America.
- Diverse mix of clients, from Fortune 100 and FTSE 100 corporations to emerging companies, and from individuals to local and national governments
- Our combination of legal and industry experience allows us to better analyze client requirements and develop the right approach for the matter at hand
- We emphasize quality, efficiency and alignment with client goals as core standards to continually improve our service delivery and the value of what we do for our clients.

Healthcare Overview

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- We have deep expertise advising:
  - For-profit and nonprofit healthcare service providers
  - Hospitals, health systems and management companies
  - Managed care networks
  - Health insurers
  - Healthcare systems and hospitals
  - Home healthcare organizations
  - Long-term care hospitals (LTCHs)
  - Manufacturers
  - Children's hospitals
  - Physician groups, physician hospital organizations, ACOs and CINs
  - Federally qualified health centers (FQHCs) and community service providers
  - Healthcare contractors
  - Rural health providers
  - Stakeholder coalitions
  - And more
- We advise in a full range of legal matters, including:
  - Accountable care
  - Antitrust counselling and defense
  - Corporate mergers, acquisitions, divestitures, joint ventures and other transactions
  - Employee plans and benefits
  - FDA regulation and enforcement
  - Health IT and HIPAA
  - Fraud and abuse and False Claims Act/qui tam litigation and counselling
  - Global data privacy and security compliance
  - Healthcare advocacy policy and legislation
  - Healthcare finance (tax-exempt and corporate)
  - Healthcare regulatory issues and compliance
  - Among others

Disclaimer

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Agenda

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- Introduction
- Overview of the Medical Device Adverse Event Reporting Requirements
- Why is FDA worried about this now?
- Highlights from FDA's Workshop – The Role of Hospitals in Modernizing Evidence Generation for Device Evaluation

Introduction

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In December 2015, FDA inspected 17 hospitals around the country and issued Form 483s to 14 of those hospitals for violations of FDA laws and regulations.

- 483s were for not having a medical device reporting procedure, not following the procedure, and/or not training staff to the procedure.
- Hospitals chosen based on knowledge of high-profile safety issues and reports of medical device adverse events without the corresponding reports from the hospitals.

FDA noted that it had yet to enforce the medical device reporting requirements on hospitals, so held a workshop last week to get input from stakeholders for the best way to work with hospitals on medical device adverse event reporting.

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Overview of the Medical Device Adverse Event Reporting Requirements

Definitions

An **adverse event** is an undesirable experience associated with the use of a medical product in a patient.

- Life-threatening injuries, deaths, hospitalization, medical intervention, etc.

A **reportable event** is an event that a user facilities become aware of that reasonably suggests that a device has or may have caused or contributed to a death or serious injury.

21 C.F.R. 803.3(o).

Definitions

A **serious injury** is an injury or illness that:

- Is life-threatening;
- Results in permanent impairment of a body function or permanent damage to a body structure; or
- 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.

21 C.F.R. 803.3(w).

Definitions

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A **device user facility** is a hospital, ambulatory surgical facility, nursing home, outpatient diagnostic facility, or outpatient treatment facility, which is not a physician's office.

21 C.F.R. 803.3(d)

A **hospital** is 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.

- Includes general, chronic disease, rehabilitative, psychiatric, and other special-purpose facilities.
- May be independent or may be operated by another medical entity.
- Hospitals are covered by the 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 events meets the criteria for reporting, the hospital must report it regardless of the nature or location of the service provided by the hospital.

21 C.F.R. 803.3(i).

Requirements for User Facility Reporting

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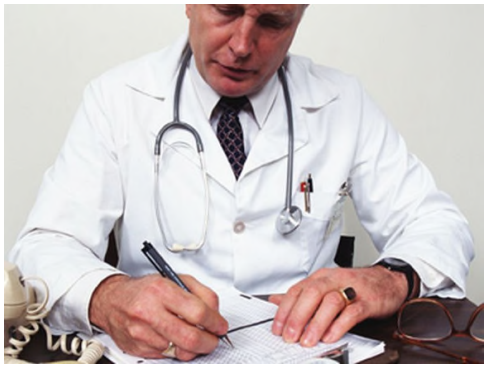
First, you need to develop, maintain, and implement a written procedure for medical device adverse event reporting (MDR).

The procedure should cover some specific items…



Requirements for User Facility Reporting

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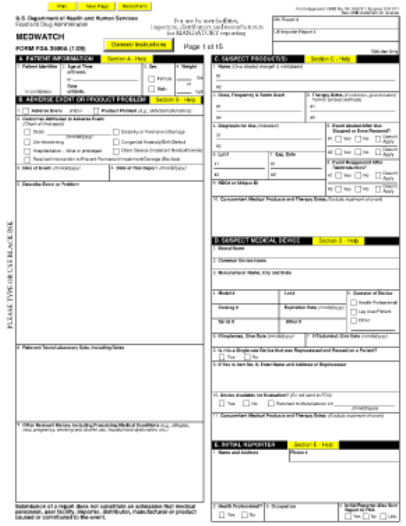
What the procedure must include:

- Internal systems that:
  - Allow timely and effective identification, communication, and evaluation of events that may be subject to MDR requirements;
  - A standardized review process or procedure for determining when an event meets the criteria for reporting; and
  - Timely transmission of complete medical device reports to manufacturers to FDA, or both if required.

21 C.F.R. 803.17


MEDWATCH

Requirements for User Facility Reporting

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What the procedure must include:

- Documentation and recordkeeping requirements for:
  - Information evaluated to determine if an event was reportable;
  - All medical device reports and information submitted to manufacturers and/or FDA;
  - Any information that was evaluated for the purpose of preparing the submission of annual reports; and
  - Systems that ensure access to information that facilitates timely follow-up and inspection.

21 C.F.R. 803.17

Requirements for User Facility Reporting

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The procedure needs to allow the user facility to establish, generate, and maintain MDR files and records. What are these?

- **MDR Event Files** are written or electronic files maintained by user facilities, and include:
  - Information or references to information related to the adverse event, including all documentation of your deliberations and decision-making processes used to determine if an event was reportable;
  - Copies of all MDR reports and of all other information related to the event that the user facility submitted to FDA or the manufacturer; and
  - Copies of all electronic acknowledgments FDA send in response to electronic MDR submissions.

User facilities must allow FDA to access and verify their MDR files and reports.

MDR event files maintained for 2 years from the date of the event.

21 C.F.R. 803.18(a-b).

Requirements for User Facility Reporting

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What information do I have to report?

- Reports of individual adverse events:
  - Device-related deaths are reported to FDA and the manufacturer.
  - Device-related serious injuries reported to the manufacturer or FDA if manufacturer unknown.
  - Must be reported within 10 working days after the day you become aware of the reportable event.
  - Use Form FDA 3500A and the MedWatch Medical Device Reporting Code Manual for adverse event codes.

21 C.F.R. 803.20

- Annual Report, content requirements at 21 C.F.R. 803.33.

Requirements for User Facility Reporting

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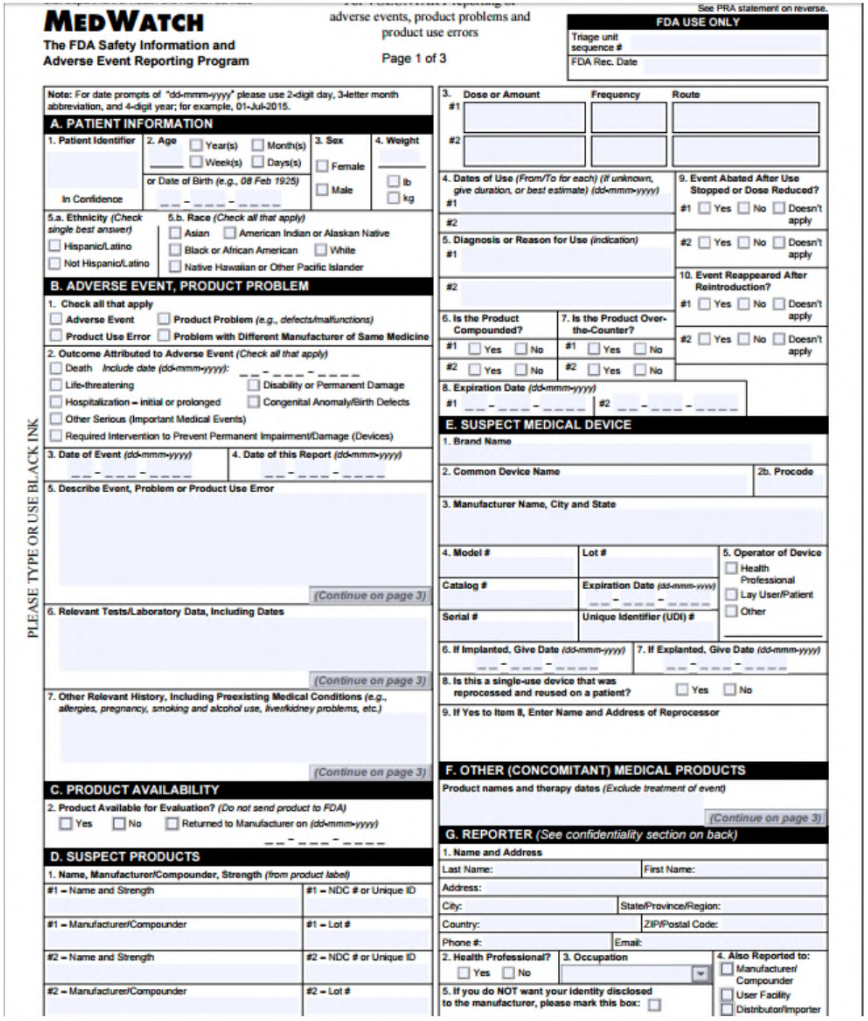


MEDWATCH
The FDA Safety Information and Adverse Event Reporting Program

adverse events, product problems and product use errors

Page 1 of 3

See PRA statement on reverse.

FDA USE ONLY
Triage unit sequence #
FDA Rec. Date

Note: For date prompts of "dd-mmm-yyyy" please use 2-digit day, 3-letter month abbreviation, and 4-digit year; for example, 01-Jul-2015.

A. PATIENT INFORMATION
1. Patient Identifier
2. Age ☐ Year(s) ☐ Month(s) ☐ Week(s) ☐ Days(s)
3. Sex ☐ Female ☐ Male
4. Weight ☐ lb ☐ kg
In Confidence
or Date of Birth (e.g., 08 Feb 1925) __ - ___ - ____
5.a. Ethnicity (Check single best answer) ☐ Hispanic/Latino ☐ Not Hispanic/Latino
5.b. Race (Check all that apply) ☐ Asian ☐ American Indian or Alaskan Native ☐ Black or African American ☐ White ☐ Native Hawaiian or Other Pacific Islander

B. ADVERSE EVENT, PRODUCT PROBLEM
1. Check all that apply ☐ Adverse Event ☐ Product Problem (e.g., defects/malfunctions) ☐ Product Use Error ☐ Problem with Different Manufacturer of Same Medicine
2. Outcome Attributed to Adverse Event (Check all that apply) ☐ Death Include date (dd-mmm-yyyy): __ - ___ - ____ ☐ Life-threatening ☐ Disability or Permanent Damage ☐ Hospitalization – initial or prolonged ☐ Congenital Anomaly/Birth Defects ☐ Other Serious (Important Medical Events) ☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)
3. Date of Event (dd-mmm-yyyy) __ - ___ - ____
4. Date of this Report (dd-mmm-yyyy) __ - ___ - ____
5. Describe Event, Problem or Product Use Error (Continue on page 3)
6. Relevant Tests/Laboratory Data, Including Dates (Continue on page 3)
7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, pregnancy, smoking and alcohol use, liver/kidney problems, etc.) (Continue on page 3)

C. PRODUCT AVAILABILITY
2. Product Available for Evaluation? (Do not send product to FDA) ☐ Yes ☐ No ☐ Returned to Manufacturer on (dd-mmm-yyyy) __ - ___ - ____

D. SUSPECT PRODUCTS
1. Name, Manufacturer/Compounder, Strength (from product label)
#1 – Name and Strength | #1 – NDC # or Unique ID
#1 – Manufacturer/Compounder | #1 – Lot #
#2 – Name and Strength | #2 – NDC # or Unique ID
#2 – Manufacturer/Compounder | #2 – Lot #

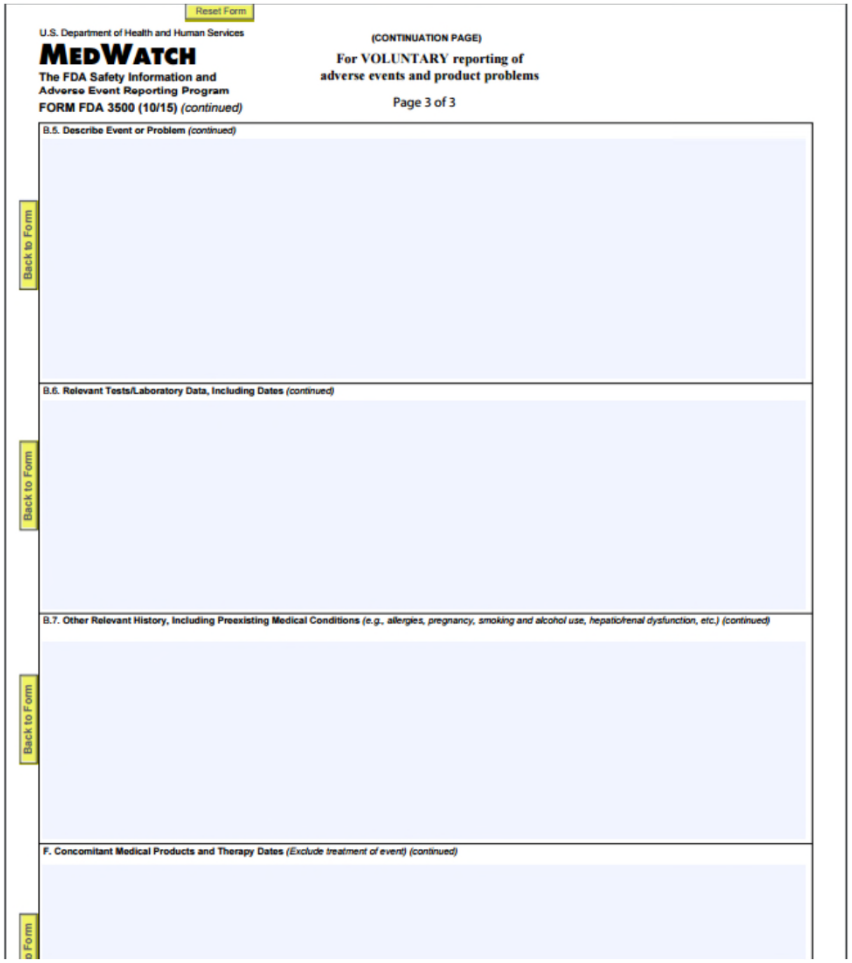
3. Dose or Amount | Frequency | Route
#1
#2
4. Dates of Use (From/To for each) (If unknown, give duration, or best estimate) (dd-mmm-yyyy)
#1
#2
5. Diagnosis or Reason for Use (indication)
#1
#2
6. Is the Product Compounded? #1 ☐ Yes ☐ No #2 ☐ Yes ☐ No
7. Is the Product Over-the-Counter? #1 ☐ Yes ☐ No #2 ☐ Yes ☐ No
8. Expiration Date (dd-mmm-yyyy) #1 __ - ___ - ____ #2 __ - ___ - ____
9. Event Abated After Use Stopped or Dose Reduced? #1 ☐ Yes ☐ No ☐ Doesn't apply #2 ☐ Yes ☐ No ☐ Doesn't apply
10. Event Reappeared After Reintroduction? #1 ☐ Yes ☐ No ☐ Doesn't apply #2 ☐ Yes ☐ No ☐ Doesn't apply

E. SUSPECT MEDICAL DEVICE
1. Brand Name
2. Common Device Name | 2b. Procode
3. Manufacturer Name, City and State
4. Model # | Lot # | 5. Operator of Device ☐ Health Professional ☐ Lay User/Patient ☐ Other
Catalog # | Expiration Date (dd-mmm-yyyy) __ - ___ - ____
Serial # | Unique Identifier (UDI) #
6. If Implanted, Give Date (dd-mmm-yyyy) __ - ___ - ____ | 7. If Explanted, Give Date (dd-mmm-yyyy) __ - ___ - ____
8. Is this a single-use device that was reprocessed and reused on a patient? ☐ Yes ☐ No
9. If Yes to Item 8, Enter Name and Address of Reprocessor

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS
Product names and therapy dates (Exclude treatment of event) (Continue on page 3)

G. REPORTER (See confidentiality section on back)
1. Name and Address
Last Name: | First Name:
Address:
City: | State/Province/Region:
Country: | ZIP/Postal Code:
Phone #: | Email:
2. Health Professional? ☐ Yes ☐ No
3. Occupation
4. Also Reported to: ☐ Manufacturer/ Compounder ☐ User Facility ☐ Distributor/Importer
5. If you do NOT want your identity disclosed to the manufacturer, please mark this box: ☐

PLEASE TYPE OR USE BLACK INK



Reset Form

U.S. Department of Health and Human Services
MEDWATCH
The FDA Safety Information and Adverse Event Reporting Program
FORM FDA 3500 (10/15) (continued)

(CONTINUATION PAGE)
For VOLUNTARY reporting of adverse events and product problems

Page 3 of 3

B.5. Describe Event or Problem (continued)
B.6. Relevant Tests/Laboratory Data, Including Dates (continued)
B.7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) (continued)
F. Concomitant Medical Products and Therapy Dates (Exclude treatment of event) (continued)

Back to Form

Requirements for User Facility Reporting

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How do I know if a death or serious injury should be reported (or, how do I know a reportable event has occurred)?

You only have 10 working days to report, so FDA thinks it is reasonable that the first report may need additional investigation.

Information that reasonably suggests a reportable event occurred:

- Any information, including professional, scientific, or medical facts, observations, or opinions.
- User facilities do not have to report an adverse event if a person who is qualified to make a medical judgment would reasonably conclude the device did not cause or contribute to a death or serious injury, or a malfunction would not cause a death or serious injury if it were to recur.
  - **This rationale, and the person making the medical judgment, would be recorded in your MDR files!**

21 C.F.R. 803.20(c).

Requirements for User Facility Reporting

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When do I really "become aware" of the potential reportable event?

- There is no requirement that a specific person or function knows of the reportable event for the user facility to know of the reportable event.

- "Reasonably known" = information found in documents the user facility possesses and any information that becomes available as a result of reasonable follow-up within the facility.

21 C.F.R. 803.30(b).

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Why is FDA worried about this now?

FDA's Current Policies

In recent years, FDA has turned to collecting and analyzing real-world evidence as a way to broaden the amount and type of data it and manufacturers receive about medical devices.

Benefits to Real-World Evidence

- Data collected as the products are actually used, which may not be how the products are studied in a very controlled clinical trial environment.
- Device UDIs can better link specific events to specific devices, making it easier for FDA and manufacturers to ferret out and fix problems.
- Manufacturers can better understand how the product performs in the real world with real users, and the device's life cycle as a result.

Where can you find the evidence? →

FDA's Current Policies

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FDA's focus on adverse events isn't new:

MedSun: Launched in 2002, created after the Food and Drug Administration Modernization Act (FDAMA) in 1997 required FDA replace universal reporting system

- 300 hospitals voluntary reporters in MedSun program.
- Primary goal: work collaboratively with clinical community to identify, understand, and solve problems with the use of medical devices.
- *Universal reporting system never limited.*

MedSun
Medical Product Safety Network

NEST: National Evaluation System for Health Technology, planning stages started in 2013 with Brookings Institution and stakeholders.

- Proposed to be a network of partners that interact with three shared resources, developed by NEST coordinating center.

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Highlights from FDA's Workshop – The Role of Hospitals in Modernizing Evidence Generation for Device Evaluation

Workshop Highlights

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FDA held a workshop for stakeholders on Dec. 5 to discuss the critical role of hospitals in the evolution of device surveillance and in creating more robust surveillance capabilities.

Challenges for Stakeholder Hospitals in Complying with Regulation:

- Data entry fatigue – Hospitals already have to report lots of things to lots of different people
  - Calls to streamline reporting system and tie with EHRs and other databases to cut down on entering the same information more than once, “sometimes-only” processes
    - Some hospital systems already doing this!
- Patient privacy and liability – How much are adverse event reports FOIA-able?
  - User error could be a device malfunction – but maybe not?
  - Very jurisdiction-dependent.

Workshop Highlights

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Some Solutions for Stakeholder Hospitals from Workshop

- Structured reporting and EHR generation that includes information that can be used across many different systems
  - Start with a conversation with system users (doctors, nurses, etc.) and software vendors to see what you can do
  - Lots of process engineering
- Barcodes and scanners for devices to make it easier to associate specific devices with specific patients
  - But this has limits too
- Link MDR Reporting systems to billing and coding systems
  - Hospitals already use reporting systems to get paid, can leverage the same information for any reporting requirements
- Staff training for users – doctors and nurses should know when to report and why

Stay Tuned…

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Thank you very much!

Any Questions?

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