

Use MedWatch to Report Sharps Injuries or Near-Injuries

Q. What is MedWatch?

A. MedWatch is the Food and Drug Administration (FDA) program for reporting serious reactions, product quality problems, therapeutic inequivalence/failure (e.g. drugs don't work in the manner expected), and product use errors with human medical products, including drugs, biologic products, medical devices, dietary supplements, infant formula, and cosmetics.

The MedWatch *Voluntary Adverse Event Report Form* can be used by health professionals and individuals for any type of human medical product, including medical sharps. Examples:

- One of your employees was hurt or had a bad outcome from using a medical device or product that your organization provided or that they encountered when providing medical care to patients.
- You were hurt or had a bad outcome or side effect (including new or worsening symptoms) after taking a drug or using a medical device or product.
- You used a drug, product, or medical device incorrectly which could have or led to unsafe use.
- You noticed a problem with the quality of the drug, product, or medical device.
- You had problems with how a drug worked after switching from one maker to another maker.

(Reference: <http://www.fda.gov/Safety/MedWatch/>)

Q. How does it relate to me?

A. If you or an employee of yours receives an injury or blood exposure from needles or other sharps, MedWatch is a good avenue for recording the injury. MedWatch should also be considered for reporting other medical device related problems such as:

- near-injuries with a device (near-miss)
- lack of clarity on how to properly use a device, or incomplete or confusing instructions for use
- safety mechanisms that fail to work properly or are dangerous to use
- allergic reactions to latex or glove additives in medical gloves
- glove failures (e.g. finding blood inside a glove with no visible holes)

MedWatch is **confidential** and the FDA does not notify employers that a MedWatch report was filed.

Q. Why report to MedWatch?

A. Your report, combined with others, provides a driving force for change:

- ♦ **Get counted!** Reporting injuries, product failures and problems provides an accounting of product shortcomings and provides a driving force for safer products. It also provides data that justify the need for better-engineered sharps devices.
- ♦ Since FDA governs medical devices, they are in a key position for **influencing development of better products**. Feedback about injuries or incidents from healthcare and home care workers can be a prompt for taking action.
- ♦ **Workers' adverse events are reportable**, just as if something had happened to a patient or client.

Q. The FDA says that MedWatch is for reporting "SERIOUS problems". What if the FDA doesn't consider my injury or exposure serious enough?

A. In order to keep effective medical products available on the market, the FDA relies on the voluntary reporting of adverse or unfavorable events. FDA uses these data to maintain safety surveillance of these products and communicates with the manufacturer. (FDA protects your identity.) Your report may be the critical action that prompts a modification in use or design of the product, improves its safety profile and leads to increased patient safety. (Reference: <http://www.fda.gov/Safety/MedWatch/>) **If you think the problem is worth reporting, it's serious.**

Q. I wasn't using the medical sharp, but I got stuck in my home care job by my client's used insulin syringe that was improperly discarded in the waste basket. Should I report this?

A. Yes. Your injury shows that typical use of the medical device—which includes people discarding unprotected used syringes—is likely to result in injuries. By reporting your injury or even a near-injury to the FDA, you are making them aware that the medical device has inherent safety shortcomings that can result in injuries and exposures to bloodborne pathogens. This is a type of quality problem.

Q. How do I use MedWatch for a sharps or needle injury or blood exposure?

A. Report your injury to MedWatch online, by phone, or submit the MedWatch 3500 form by mail or fax. Forms and instructions for using MedWatch are available by calling the FDA (800-FDA-1088) or online:

<http://www.fda.gov/Safety/MedWatch/HowToReport/default.htm>

Online: <https://www.accessdata.fda.gov/scripts/medwatch/>¹

To get started, you will select whether you are reporting as “Health Professional” or “Consumer/Patient”²

Phone: **Call the FDA at 1-800-FDA-1088** to report by telephone

Mail or Fax: Submit 3500B (user-friendly form for consumers) or Form 3500 (general form for healthcare professionals and consumers). You can call the FDA to have a form mailed to you or download the form from the FDA website links shown below³:

Form 3500B is designed specifically for consumers to report an adverse event or serious problem to FDA.

In this instance, “consumers” would be any non-medical person who is adversely affected by a medical device (for example, the patient, personal care attendant, family member).

<http://www.fda.gov/Safety/MedWatch/HowToReport/ucm053074.htm>

The general Report Form 3500 may be used by healthcare and consumer reporters.

<http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM163919.pdf>

When you prepare your report, **be very specific about the device** – manufacturer, model, type, size, and any other information available. If you don't know the specifics about the device, provide as much information as you can. Sketches, measurements, product colors, and the like can all be helpful information. **Describe how the device resulted in an injury, near-injury or unsafe situation.**

The Safe Home Care and Hospitals Program is a research group within the University of Massachusetts Lowell, Department of Work Environment. Please send comments and questions to: SafeHomeCare@uml.edu. For more information, visit our website: www.uml.edu/SafeHC

¹ Sometimes links change; if this link doesn't work, do a web search using the phrase *MedWatch Online Voluntary Reporting Form*

² A “consumer” is someone who is reporting as a non-healthcare professional.

³ Sometimes web addresses change. You may also do a web search for “FDA form 3500B” or “FDA form 3500”