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Privileged Communication

Winter 2009 **A Complimentary Publication**

The Safe Medical Devices Act in a Nutshell...

Who MUST report?

- Hospitals, ambulatory surgical facilities, nursing homes, home health agencies, ambulance providers, rescue groups, skilled nursing facilities, rehabilitation facilities, hospices, psychiatric facilities and all other outpatient treatment and diagnostic facilities that are not a physician's office.
- Manufacturers of medical devices.
- Distributors of medical devices (at present, covered by different regulations).

Who is exempt from the reporting requirement?

Physician's offices and "groups performing functions similar to physician's offices" such as dental offices and offices of other health care practioners (e.g., chiropractors, optometrist, nurse practioners, school nurse offices, employee health clinics, free-standing care units).

What events MUST be reported?

- *For health care facilities:* Information from any source that reasonably suggests that a device has or may have "caused or contributed" to the death or serious injury of a patient or employee of the facility. Deaths must be reported directly to the FDA and the manufacturer, if known. Semi-annual reports must be submitted to the FDA. "Caused or contributed" is defined by the regulations to mean "that death or serious injury was or may have been attributed to a medical device or that a medical device was or may have been a factor in a death or injury.
- *For Manufacturers:* Information from any sources that reasonably suggests that a device marketed by the manufacturer 1) has caused or contributed to a death or serious injury, or 2) has malfunctioned and such device or a similar device marketed by the manufacturer would be likely to cause or contribute to a death or serious injury, if a malfunction were to recur.
- *For Distributors:* Information from any source that reasonably suggests that there is a probability that a device marketed by the distributor has 1) caused or contributed to a death, or serious injury, or 2) has malfunctioned and such information reasonably suggests that there is a probability that such a device or any other device marketed by the distributor would cause a death, serious injury, or serious illness if the malfunction were likely to recur. The FDA says it will change the distributor reporting requirement to conform to those in the final rule for manufacturers and users.

To whom must reports be submitted?

- *For health care facilities:* Device-related deaths must be reported directly to the FDA and to the manufacturer. Serious injuries must be reported to the manufacturer, or to the FDA, if the manufacturer is unknown. Semi-annual summaries must be submitted to the FDA.
- *For Manufacturers:* All reports must be made directly to the FDA.
- *For Distributors:* Reports of death and serious injury must be made to the FDA, and a copy must be sent to the manufacturer. Reportable malfunctions must be submitted directly to the manufacturer.

For more information: see these web pages:

- *http://www.fda.gov/cdrh/mdr/*
- *http://www.fda.gov/medwatch/*◆

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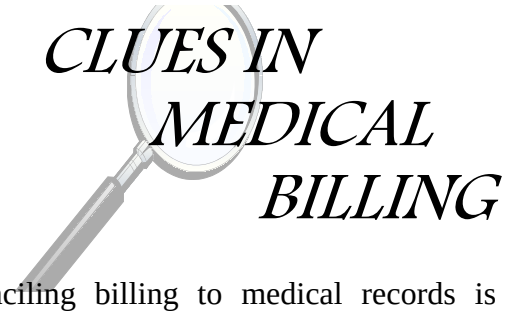

Reconciling billing to medical records is a time consuming process but it can supply insights into your client's case which may not have occurred to you.

One aspect which may become clearer with these records is the strength and frequencies of medication. The bill may reveal that a dose of medicine was stronger than what the physician ordered, thereby causing an "overdose" situation. It may reveal more medications were charged for than were ordered to be given. All these issues are clarified by reconciling the bill with the medication records to doctor's orders.

Of course another benefit of reconciling the bill would be discovering expenses not actually incurred. Eventually all unrelated expenses and charges for drugs, supplies, or treatments that were not provided to your client should be deleted from the bill.

Often clerks and/or secretaries are burdened with this reconciliation. They struggle to make sense of stacks of records written in medical terms about medicines and procedures which, to your staff member, are probably Greek! As a result of this false economy, you lose a staff member for a long period of time. More importantly some critical clues from those records can be easily overlooked through lack of medical education.

Your Legal Nurse Consultant can provide an efficient, professional and thorough service in this area. For more information, please contact us at (505) 898-5854.

Medical Abbreviations

Did you know that the abbreviation "SR" has 15 possible meanings, such as sedimentation rate, sinus rhythm, side rails, see report, and slow release to name a few. **"Medical Abbreviations"** by Neil M. Davis, is a valuable reference, listing of over 30,000 medical abbreviations and meanings. Also included is a cross referenced list of 3400 generic and brand drug names. This is a "must have" for anyone who reviews medical records. Keep it in your desk drawer for quick reference. Prices are reasonable so that everyone can have their own copy. To order, contact Neil Davis at 888-333-1862 or his web address: http://www.neilmdavis.com. The newest edition, also gives the purchaser free access to his medical abbreviations web site for 24 months, which is updated with about 100 new entries every month. ◆

We would like to wish you and your staff a Happy and Prosperous New Year. We look forward to the opportunity to work with you in the coming year.

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