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Ephedra: It's Natural, But is it Safe?

Ephedra, also known as Ma Huang, has been the center of controversy for several years now. It is a plant species that has been used for thousands of years in traditional Chinese medicine to treat asthma and respiratory infections. The main components of ephedra are ephedrine and pseudoephedrine. Ephedrine is a bronchodilator and stimulator of the sympathetic nervous system, relieving spasm and inflammation in the airways. Pseudoephedrine is a nasal decongestant. The controversy stems from ephedrine's adrenaline-like nervous system stimulation, which leads to constriction of the blood vessels; and increased blood pressure, heart rate, and force of heart contractions. These can cause potentially serious adverse effects.

Ephedra can be found in many over-the-counter dietary supplements promoting decreased appetite and increased energy. Under the Dietary Supplement Health and Education Act (DSHEA) of 1994, the FDA cannot regulate these herbal supplements as it does pharmaceuticals. Therefore, evidence of the product's safety is not required by manufacturers before marketing. And, in order to take regulatory action against a supplement, the government must prove it is not safe. Interestingly, the main component ephedrine, when chemically synthesized, is regulated as a drug.

Since 1994, the FDA has received numerous reports of adverse effects of ephedra containing supplements. These include nervousness, dizziness, tremor, blood pressure and heart rate alterations, headache, gastrointestinal distress, chest pain, myocardial infarction, seizures, psychosis, and death. Many of these have occurred in apparently healthy persons, and many seem to be associated with strenuous exercise or other stimulants like caffeine. Previous attempts by the FDA to restrict ephedra access have been rejected due to lack of statistically significant support from available evidence. However, evidence is only increasing, including more than 30 deaths of active military personnel prompting removal of ephedra from military shelves.

Results from a RAND Corporation study, as well as others, provide evidence that ephedra may be associated with health risks. But more studies would be useful as more definitive evidence is needed. Still, the Department of Health and Human Services along with the FDA has recently announced actions to address concerns about the safety of ephedra. These include:

- Warning letters to ephedrine manufacturers that any claims their products make regarding athletic performance or changes to the human body must be truthful and not misleading, and must not claim to treat or cure a disease.
- A proposed black box warning label that clearly warns about serious adverse events and death reports after using ephedra.
- The seeking of rapid public comment from health professionals, supplement manufacturers, and the public regarding further data on the safety of ephedra. This is to provide a complete picture of the risks of ephedra and to determine if they are significant or unreasonable.

Adverse event reports and increasing evidence support the mounting concern that ephedra containing supplements may pose a risk to the health of those using them.

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Hospital Records Simplified

The intent of this article is to provide an overview of key elements of the hospital record thereby allowing the reader to recognize significant information in order to provide a complete and accurate account of medically related events surrounding personal injury and professional malpractice litigation.

One of the key sources of information for litigation involving personal injury and professional malpractice is the client's hospital record. Hospital records are legally required documents that have specific purposes and must contain specific types of information. Since information contained in a hospital record can either support or weaken a claim it is imperative that all possible sources of a client's records are explored and investigated. The information should then be reviewed and summarized as it relates to the case. A legal nurse consultant has the unique experience necessary to provide the attorney with a comprehensive review and analysis of the hospital record.

Components of Medical Records

The standards for medical record documentation to which hospitals must comply are clearly defined by both the Joint Commission for Accreditation of Healthcare Organization (JCAHO) and by the

Department of Health and Human Services. As a result medical records may differ widely in appearance and format yet they contain standardized information. The components of the hospital record are described below and are listed in the order they most commonly appear in the hospital record.

Admission Record: Contains all patient demographic information including address, social security number, marital status, emergency contact(s), and insurance. This document also contains the admission diagnosis, admitting physician, and the admission and discharge dates.

History and Physical (H&P): Contains the patient's current complaint, past medical history, family history, social history, including habits such as tobacco, alcohol and drug use, review of systems (patient's complaints, i.e., nausea, vomiting, sweating, etc), physical exam, diagnosis and the treatment plan. The admitting physician most often completes the History and Physical though other health care providers such as nurse practitioners (NP) and physician assistants (PA) can prepare this information.

Discharge Summary: This document provides an overview of the hospital course and contains the final diagnosis. Included are any procedures, special diagnostic studies, and operations the patient underwent while hospitalized. The Discharge Summary includes complications, condition on discharge, discharge medications and follow up instructions. This report is a dictated summary that must be prepared within thirty days of that patient's discharge.

Consultations: Documentation by physician specialists, such as cardiologists, neurologists, etc. describing the patient's condition and treatment recommendations. A consultation is generally requested when a patient has a complicated disease condition requiring the care of a specialist.

Progress Notes: Contain a chronological narrative of the patient's condition and response to treatment. Both objective (clinical observations) and subjective (patient's complaints) information are included. Notations must be made daily in acute care facilities. The more critically ill a patient is, the more frequently progress notes are made. All members of the patient care team, i.e. specialists, interns, residents, pharmacist, social workers, dietitians, etc. may make entries in this section of the record.

Physician Orders: Contains orders for all treatments, tests, medications and procedures for the patient while hospitalized. These orders may include preprinted treatments, medications, tests etc. called standing orders, which a physician signs at the time of initiation. Physicians as well as physician assistants and nurse practitioners with hospital privileges, may document physician orders. Registered nurses may take telephone and verbal orders which are documented on the physician order form. The physician must sign these, usually within 24 hours of issue.

Surgery Documents: This section contains the anesthesiologist's preoperative exam, a dictated operative report, record of the operation, anesthesia records, and recovery room nursing notes. The surgical consent is contained in this section of the hospital records. Perioperative Nursing Notes, also contained in this section includes a record of the counts for needles and sponges, equipment use and manufacture identification numbers of implants, pacemakers etc.

Nurses Notes: A record of the care administered to the patient while in the hospital. Nurses' notes are made over a 24-hour basis. Initial patient assessments are done at the beginning of each work shift and changes from baseline are noted. Patient treatments, medications given, and other interventions are recorded. It often makes up the largest portion of the medical record. Flow sheets are a common

format used in specialized care units such as ICU (intensive care unit) and CCU (coronary care unit).

Graphic Sheets: A record of the patient's temperature, pulse, respiratory rate and blood pressure. These sheets also contain additional information such as weight, intake and output of fluid.

Medication Administration Record (MAR): A list of all medications administered to a patient while in the hospital. These records reflect the medication's name, dose, route and the time given.

Intravenous Therapy: A record of all fluid, blood and blood products. Includes the date, start and completion times, amount of fluid or blood product infused, nurse's initials, etc.

Laboratory, X-Rays, Special Tests: All laboratory results, radiology reports, and pathology reports can be found in this section. Additional tests, such as CT Scans, EEGs, MRIs and cardiac testing are also located in this section.

Emergency Department: These records are usually located in the back of the chart when the patient was admitted through the emergency room (ER) or emergency department (ED). They describe the care and treatment provided while in the ER. This medical section may also contain records supplied by paramedics (EMT-Ps) or other rescue personnel (i.e. fire department, flight crew).

Ancillary Department: Notes from many of the specific disciplines within the hospital such as respiratory, dietary, social services, discharge planning, physical, speech and occupational therapy can be included in the chart when pertinent.

Miscellaneous Form: Other forms which may be found in a patient's charts are informed consents, advance directives, protocols for specific procedures, etc.

The hospital record can certainly be overwhelming and intimidating to the uninitiated reader. Hopefully this brief summary provided some information to facilitate locating the necessary information to provide an accurate description of the events surrounding the hospitalization which may have some bearing on the litigation process. A legal nurse consultant has the knowledge and expertise necessary to decipher the information contained within the record and provide the attorney with insights necessary for a comprehensive understanding of the medical issues inherent in a personal injury or medical malpractice case.

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