Proper Documentation Can Derail a Lawsuit

Many charts lack information about the physician's role and decision-making process.

BY SHERRY BOSCHERT
San Francisco Bureau

CABO SAN LUCAS, MEXICO — What you put in a patient's medical record could drive a potential lawsuit to court or away from litigation, Dennis J. Sinclitico, J.D., said.

"You can't control the labor and delivery. The one thing you can do is control what appears in the medical record," he said at a conference on obstetrics, gynecology, perinatal medicine, neonatology, and the law.

The biggest problem he said he sees in documentation is incompleteness—charts that lack important information about the physician's role, decision-making process, and justifications for management.

Many physicians complain that they don't have time to write sufficient records, said Mr. Sinclitico, a defense attorney, in Long Beach, Calif. "Would you rather spend the time in court for 12 weeks, 5 days a week, from 9 a.m. to 5 p.m.?" he asked.

Adequate documentation may be less than physicians imagine. Writing "Matter was discussed with patient" is better than saying what you discussed, because you risk leaving something out of the record. Writing "Exam was done" or "Doctor was notified" is better than giving details because these statements free you to add details orally later if questioned, he said at the meeting, sponsored by Boston University and the Center for Human Genetics.

Rules concerning medical documentation may differ somewhat from state to state, he said, but the following do's and don'ts will help create records that should help offset potential lawsuits:

► **Don't destroy evidence.** No matter how bad the fetal monitoring strip looks, resist the temptation to make it disappear. In some states, destroying a record is an added offense, exposing you to additional liability.

► **Don't ever change the record.** "It's simple advice, but I see it happen over and over again," Mr. Sinclitico said. Sophisticated technology can detect alteration of records. In some states, changing a record is an added offense.

► **Do label any addition to the chart as a "late entry."** Late entries are common when there's a good reason why the physician can't adequately document things as they happen, such as being busy with the patient's care. Ideally, wait and do all the documentation as a late entry once you're able, rather than writing some contemporaneously and adding some later.

"To the extent that it's a self-serving addition, the lawyers will hammer you with it. To the extent that it attempts to be objective about what occurred and the timing of what occurred, then it's appropriate," he said.

► **Do time and date your entries in the record.** Chronicity is very important in reconstructing how things happened. Don't rely on memory; recall is faulty.

► **Do include significant positives and negatives from the patient's history and physical exam.** "To the extent these form a basis for clinical judgment, they better be on the chart," he said. Often records lack any mention of the history, or references to the history are illegible.

► **Do indicate that you reviewed the laboratory data and the fetal monitoring strip.** Physicians frequently neglect to note these things in the record.

► **Do describe your management plan well.** Provide enough detail to support the orders you give.

► **Don't editorialize about the patient or anyone else.** Personal comments are a prescription for legal disaster, Mr. Sinclitico said.

► **Don't add risk management comments like, "We need to do better" or "There weren't enough beds available."** Most institutions use a report of unusual occurrence or a similar form to gather risk-management information. If you make your comments in that arena, it is unlikely that they will be accessible to lawyers.

► **Don't include peer-review comments.** Saying things such as "Dr. Jones failed to arrive in a timely fashion" is probably going to get Dr. Jones and you in legal trouble. "If it's a matter that you feel strongly about, and it requires peer-reviewed evaluation, use the appropriate hospital committees to take that matter up," Mr. Sinclitico advised. ■

Breaux Calls for Individual Health Insurance Mandate

BY MARY ELLEN SCHNEIDER
Senior Writer

NEW ORLEANS — The real social crisis facing America right now isn't fixing Social Security but tackling the problem of the uninsured, former Sen. John Breaux said at the annual meeting of the American Academy of Dermatology.

"The crisis that I see in health care in this country is the fact that we have 44 million Americans who have no form of health insurance whatsoever," he said.

And the crisis is likely to get worse as more and more companies are opting not to provide health insurance to their employees, said Mr. Breaux, a Democrat who represented Louisiana in the U.S. Senate for the past 18 years.

But the problem isn't how much money is being spent on the system, he said, it's the way the system is organized. Currently, most individuals receive their health coverage either through their employer or through Medicare, Medicaid, or the Department of Veterans Affairs. If they don't fit into one of these eligible groups, or their employer doesn't provide coverage, they are unlikely to be insured.

One way to get away from this traditional system of coverage would be to create a federal mandate that every individual must have health insurance, Mr. Breaux said. Under this type of plan, the government would offer subsidies to low-income individuals to purchase coverage.

The government would also need to create some type of state or multistate purchasing pools and ensure that the system prevents adverse risk selection so that insurance could be purchased at a reasonable price, he said.

Mr. Breaux compared such a plan to the existing requirement in most states that drivers must have a liability insurance policy. "People understand that and they have accepted that," he said.

Under such a system, if someone without insurance sought care in an emergency department, he or she would be enrolled in a purchasing pool at that time, he said. Or people might need to show proof of health insurance when they get their driver's license.

Mr. Breaux said that such a plan would help to move away from the current segmented system of health care and the waste, fraud, abuse, and duplication that accompanies each of those separate bureaucracies.

And providing insurance to more Americans would cut down on overall costs because it would allow more people to have access to preventive treatments. The best way to get a handle on health care costs is through disease management, Mr. Breaux said, but you have to get the patients into the physician's office to do that.

While it's unlikely that such a system would be enacted anytime soon, it's a worthy goal, Mr. Breaux said.

"As we try to get a handle on the costs, we have to move away from the fact that we can just regulate it to death and control costs through regulation," he said. ■

Congressional Hearing Examines Ways To Bolster Drug Safety Through FDA

BY JOYCE FRIEDEN
Associate Editor, Practice Trends

WASHINGTON — Congress is considering giving the Food and Drug Administration more authority over the pharmaceutical companies it deals with, but some legislators are warning against doing too much too fast.

"Changes to drug safety … must be carefully considered to make sure they don't unduly impact patient access," Sen. Mike Enzi (R-Wyo.), chair of the Senate Health, Education, Labor, and Pensions Committee, said at a hearing on FDA oversight. "Congress needs to engage in strong oversight to maintain public confidence in the FDA."

Sandra Kweder, M.D., deputy director of the Office of New Drugs at the FDA's Center for Drug Evaluation and Research, told the Senate committee that in order to ensure drug safety, it would be helpful if the FDA had more clout. She noted that it took a lot of back-and-forth haggling just to get some earlier warnings added to the label.

"The most important lapse [with the safety concerns surrounding Vioxx] was the delay it took to get the information into the labeling; it took over a year," she said. "I think stronger ability to require changes in labeling would be very helpful."

The committee's ranking member, Sen. Edward Kennedy (D-Mass.), also spoke in favor of giving the agency greater labeling authority. "The FDA needs clear authority to require relabeling of a drug after approval once a risk is found," he said. "Negotiations with the drug company should never delay [that]."

Some observers said that although giving the agency more authority over label changes is a good idea, it only goes so far. "We all know product labeling does not change provider behavior very much," said Arthur Levin, director of the Center for Medical Consumers in New York and the consumer representative on the FDA's Drug Safety and Risk Management advisory committee. Even if FDA does get more labeling authority, "we shouldn't count on it protecting the public from harm," Mr. Levin said at a teleconference announcing the release of a new survey on consumer attitudes toward the FDA.

The survey of 1,000 adults nationwide was performed by pollster Celinda Lake and sponsored by a coalition of consumer groups. The results showed that only 14% of respondents had a great deal of confidence in the agency's ability to ensure the safety of prescription drugs. And 48% of respondents believed the FDA was too influenced by the industries over which it has jurisdiction.

Another subject discussed at the Senate hearing was the secrecy of clinical trial data. "I'd like to emphasize the importance of open access to data from clinical trials, including negative trials and unpublished research," David Fassler, M.D., a child and adolescent psychiatrist in Burlington, Vt., who testified on behalf of the American Academy of Child and Adolescent Psychiatry and the American Psychiatric Association.

In 2004, when Dr. Fassler testified on the question of whether there was a link between selective serotonin reuptake inhibitors (SSRIs) and suicide, "there were only four studies in the published literature on [the use of] SSRIs in adolescents. But I later learned that there were 11 unpublished studies whose results had been submitted to FDA. Parents clearly need access to this kind of evidence." ■