POLICY & PRACTICE

More Angioplasties Than CABG

The number of angioplasties almost doubled from 1993 to 2005, while the number of coronary artery bypass graft operations was on the decline over the same period, according to the latest data from the Agency for Healthcare Quality and Research's Healthcare Cost and Utilization Project. By 2005, there were about 800,000 percutaneous procedures each year, while only about 278,000 CABG procedures were performed. Even though the length of stay for an angioplasty had decreased to about 2.7 days in 2005, hospital charges rose 50% from 1993 to 2005, to about $48,000, adjusted for inflation, according to the AHQR. Coronary artery disease accounted for just over 1 million hospitalizations in 2005, making it the third-leading reason for a hospital stay.

Boston Settles Guidant Claims

Boston Scientific has agreed to pay $16.75 million to settle with attorneys general in 35 states and the District of Columbia, all of whom were investigating the circumstances surrounding recalls of three Guidant Corp. defibrillators: the Ventak Prizm 2DR Model 1861, Contak Renewal Model H135, and Contak Renewal 2 Model H155. The company admits no liability, but it has agreed to extend the supplemental warranty on the devices for 6 additional months. Boston Scientific, which acquired Guidant last year, also said in a statement that it would continue to work on making changes recommended by Guidant's independent panel, including establishing a patient safety advisory board and improving communications about product performance.

... And Is Warned on Stent Study

The Food and Drug Administration has issued a warning letter to Boston Scientific, citing the company's failure to report two of at least five deaths that occurred during a phase I U.S. study of the TriVascular stent for abdominal aortic aneurysms. The company also did not report to the agency in a timely manner on stent fractures, which occurred in at least 25 patients, according to the FDA letter. The study was initiated in 2003 by TriVascular Inc., which Boston Scientific bought in 2005. Boston Scientific cancelled the trial in 2006, and abandoned development of the stent. But the company is still required to submit required paperwork to the FDA, including progress reports on patient deaths, and a corrective action plan to address the deficiencies cited by the agency.

Bill Seeks MD Gift Disclosure

Legislation in the Senate would require quarterly disclosure of gifts, honoraria, travel, and other payments to physicians by pharmaceutical, medical device, and biotechnology manufacturers. The bill, S. 2029, was introduced by Sen. Chuck Grassley (R-Iowa) and Sen. Herb Kohl (D-Wisc.) and would apply to manufacturers with more than $100 million in gross revenues. The U.S. Health and Human Services Department would be required to make the disclosure data available on the Internet. Penalties would range from $10,000 to $100,000 per violation. Ken Johnson, senior vice president of the Pharmaceutical Research and Manufacturers of America, said in a statement that his group had not yet reviewed the bill but that contact with physicians is essential for education purposes. The group's guidelines suggest gifts to physicians should not exceed $100. The American Medical Association had also not yet read the proposal, but in testimony earlier this year, noted that it has extensive guidelines on accepting anything from industry.

Rise in Adverse Drug Event Reports

The number of serious and fatal adverse drug events reported to the FDA more than doubled between 1998 and 2005, according to a report in Sept. 10 issue of the Archives of Internal Medicine. The agency defines a serious adverse event as an one resulting in death, a birth defect, disability, or hospitalization, or one that requires intervention. During the 8-year period, the number of reported serious adverse drug events increased from 34,966 in 1998 to 89,842 in 2005, a 2.6-fold increase; the number of reported deaths during that time increased 2.7-fold, from 5,519 to 15,107. The increase was largely a result of expedited reports from manufacturers of serious events not included on the label. Contrary to expectation, drugs related to safety withdrawals accounted for a "modest share" of reported events and declined over time. Of the 15 drugs most frequently cited in fatal events, there was a "disproportionate contribution of pain medications [7] and drugs that modify the immune system [4]." Drugs named in serious adverse drug events spanned a variety of classes, but within that group, events tied to 13 new biotechnology products increased almost 16-fold, from 580 in 1998 to 9,181 in 2005.

—Alicia Ault

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