

POLICY & PRACTICE

Policing 'Gainsharing'

A proposed "gainsharing" arrangement between a hospital and several cardiology groups would violate federal statutes, according to an advisory opinion from the Department of Health and Human Services Office of the Inspector General (OIG). However, OIG will not seek sanctions against the hospitals or cardiology groups because the proposed arrangement includes proper safeguards to protect against inappropriate reductions in services. Under the proposed gainsharing arrangement, a hospital would share with each of eight cardiology groups a percentage of the hospital's cost savings from the cardiology group's implementation of a number of cost reduction measures in cardiac catheterization laboratory procedures. The Office of the Inspector General found that the arrangement would amount to an improper payment to induce reduction or limitation of services and would potentially generate prohibited remuneration under the antikickback statute. However, OIG will not take action because the arrangement includes safeguards such as utilizing historic and clinical measures to establish a floor for savings to any cardiology group. The proposed arrangement is transparent and would allow for public scrutiny and individual physician accountability for any adverse effects, according to the OIG opinion. "Simply put, many 'gainsharing' plans present substantial risks for both patient and program abuse—risks that are not present in the proposed arrangement," according to the OIG opinion. The advisory opinion, which is available online at <http://oig.hhs.gov/fraud/docs/advisoryopinions/2005/ao0504.pdf>, does not apply beyond this specific arrangement.

Antismoking Campaign

A group of former top federal health officials has asked a federal court to order the major tobacco companies to fund an independent public education and smoking prevention campaign directed at children and teens. In February, as part of an ongoing government case against the tobacco companies, the U.S. Court of Appeals for the District of Columbia Circuit ruled that the government could not require the companies to turn over \$280 billion in profits. However, the court offered the option of pursuing other remedies. The Citizens' Commission to Protect the Truth—a group of former U.S. secretaries of Health, Education, and Welfare, U.S. secretaries of Health and Human Services, U.S. surgeons general, and directors of the Centers for Disease Control and Prevention—submitted an amicus brief to the court offering the option of requiring the tobacco companies to fund the American Legacy Foundation's truth campaign. The truth campaign is the largest national youth smoking prevention campaign in the country.

Cost of New Drug Benefit

National health care spending costs will remain stable over the next 10 years, although public programs will account for half of total spending, in part because of the new Medicare Part D prescription drug benefit, according to a report by the Centers for Medicare and Medicaid Services. The agency claims that the drug benefit—which kicks in in January—is expected to "significantly" increase prescription drug use and reduce out-of-pocket spending for older patients without causing any major increase in the health care spending trend. However, the new benefit will result in a significant shift in funding from private payers and Medicaid to Medicare. Medicare spending is projected to grow almost 8% in 2004 and 8.5% in 2005, due to several changes in the program under the Medicare Modernization Act, such as positive physician updates and higher Medicare Advantage payment rates.

Clinical Trial Registry Legislation

Sen. Chuck Grassley (R-Iowa) and Sen. Christopher Dodd (D-Conn.) have introduced legislation to require drug makers to register clinical trials about prescription medicines. The bill is similar to legislation Sen. Dodd introduced in the last Congress, but it stipulates that www.clinicaltrials.gov be maintained as a registry for patients and physicians seeking information about ongoing clinical trials for serious or life-threatening diseases, and requires the Food and Drug Administration to make internal drug approval and safety reviews publicly available. Doing so would make the system for ensuring drug safety "more transparent and more accountable," said Sen. Grassley, chair of the Senate Finance Committee. Trade groups representing pharmaceutical companies have already pledged to use a voluntary clinical trials registry and results database by mid-2005.

Perceptions of the Drug Industry

Prescription drugs may be improving patients' lives, but 70% of 1,201 adults polled in a Kaiser Family Foundation survey thought the drug industry cared more about profits than people. Only 24% thought the companies were most concerned with developing new drugs that save lives and improve quality of life. People also blame drug companies for rising health care costs: Nearly 60% said prescription drugs increased overall medical costs because they were so expensive, compared with the 23% who said drugs lowered medical costs by reducing the need for expensive medical procedures and hospitalizations. In an earlier poll, Kaiser found that people were more likely to cite drug company profits than other causes as the major cost of rising health care. While not as popular as physicians or hospitals, drug companies were in fact viewed more favorably than oil or tobacco companies, according to the survey.

—Mary Ellen Schneider

New Federal Law Expected To Limit Class-Action Suits

BY JOYCE FRIEDEN
Associate Editor, Practice Trends

WASHINGTON — People who have suffered adverse outcomes due to drugs or medical devices may face more delays in suing manufacturers for damages now that federal class-action lawsuit legislation has been signed into law.

The law, known as the Class Action Fairness Act of 2005, would move from state court to federal court any class-action lawsuit in which the amount of damages claimed exceeded \$5 million and involved citizens in different states. The law also outlines circumstances in which federal courts can decline to hear class-action cases.

Proponents of the law, which passed quickly in both the House and Senate, say it will help decrease the number of "junk lawsuits" that are clogging the state courts.

"America's employers and consumers are the big winners," Tom Donohue, president and CEO of the U.S. Chamber of Commerce, said in a statement. "Reform of the class action lawsuit system will reduce frivolous lawsuits, spur business investment, and help restore sanity to our nation's legal system."

Critics of the bill, however, say that it will deprive citizens of their right to sue when they are injured by a defective product. "There are only 678 federal trial judges in the system, but there are 9,200 state judges in courts of general jurisdiction," said Jillian Aldebron, counsel and communications coordinator for Public Citizen's Congress Watch, a citizen watchdog group. "So you're talking about cases ordinarily divided up among 9,200 judges and squeezing them into the courtrooms of 678 judges.

Even if they are willing to hear the cases, it's going to take years, and these cases take years in state court [already]."

Physician organizations, including the American Medical Association and the American College of Physicians, have declined to take a stand on the bill; their efforts are more focused on tort reform legislation affecting medical malpractice cases. But consumer groups, such as the Campaign for Tobacco-Free Kids, lamented the effect the bill would have on health care-related cases. "Class-action lawsuits have been an important tool in efforts to hold the tobacco industry accountable," the group's president, Matthew L. Myers, said in a statement. "This bill will deprive citizens of a state of the right to have their cases heard in their own courts, further overburden the federal courts, and make it more difficult for tobacco companies to be held accountable for years of misleading Americans about the dangers of tobacco."

Senior citizens' lobby AARP also opposed the bill. "There wasn't an adequate basis for consumers no longer having the option of bringing a multistate case in state court," said Larry White, senior legislative representative. "When you in essence say that the federal courts will have jurisdiction ... knowing the federal courts oftentimes don't certify those cases, you're in essence saying people who have been genuinely harmed don't have options."

According to the Bush administration, the law will help consumers. "The bill will remove significant burdens on class-action litigants and provide greater protections for the victims whom the class-action device originally was designed to benefit," the administration said in a statement. ■

HSAs Affect Health Care Utilization

Health savings accounts and other consumer-directed insurance products can help lower health care utilization and encourage better health behaviors, according to an industry expert.

Consumers "begin to recognize that the behaviors that they have can lead to a health outcome that can actually cost them money in the long run," said Doug Kronenberg, chief strategy officer for Lumenos, an Alexandria, Va.-based company that sells health savings accounts.

"And therefore they begin to think about changes in their behavior that can impact that health care," he said.

When an employer or insurer combines that with a program showing consumers the financial benefits of changing their behavior and offers support tools, consumers really become engaged in their health care, Mr. Kronenberg said in a teleconference sponsored by the Kaiser Family Foundation. For example, employers can create financial incentives for consumers to complete a health risk assessment.

Health savings accounts (HSAs) were authorized under the Medicare Modernization Act of 2003 and are portable ac-

counts that consumers can use to pay for certain qualified medical expenses.

The accounts are generally offered in conjunction with a high-deductible insurance plan, and both consumers and employers can contribute to the accounts. HSAs and similar accounts, such as health reimbursement accounts, can also create big savings for employers, Mr. Kronenberg said. With these types of plans, consumers tend to see the money as their own, and utilization of health care services typically drops.

But Mila Kofman, J.D., assistant research professor at the Health Policy Institute at Georgetown University, Washington, said that HSAs coupled with high deductible plans are just shifting the cost burden for health care from the insurer and the employer to the consumer.

One of the possible pitfalls is that consumers who are facing large deductibles each year will forego needed medical care because they can't afford it. This could raise the cost of health care if consumers skip or delay screenings and other preventive care that identify problems early.

—Mary Ellen Schneider