POLICY & PRACTICE

ACC 2007 Congressional Agenda

Replacing the sustainable growth rate tops the legislative agenda at the American College of Cardiology, Dr. Jack Lewin, the new college CEO, said at a briefing last month. "We have to look for a stable approach" to physician payment, said Dr. Lewin, adding that it's "a big challenge." When asked about a draft report on alternatives from the Medicare Payment Advisory Commission (MedPAC) that is in circulation, he said, "What I've read doesn't inspire me." Dr. Lewin, formerly CEO of the California Medical Association, said the ACC recruited him largely because of his experience with benchmarking and pay for performance. Working with Congress and MedPAC on developing "reasonable" quality reporting measures will also be a priority for ACC, along with promoting interoperability of health information technology and improving access to care, he said.

Heart Disease Still No. 1 Killer

The American Heart Association's latest statistics show that heart disease is still the top killer in the United States, with stroke coming in at no. 3. The AHA's 2007 report contains data from 2004, the most recent year for which statistics were available. Cardiovascular disease is the underlying cause for 36% of deaths in America, according to the report. Incidence of stroke, which affects 700,000 people a year, is due to rise precipitously: By 2032, an estimated 275,000 Americans will die from ischemic stroke, a 100% increase from 2000, the AHA said. The AHA wants more patients and physicians to get the message that at least as many women are affected by cardiovascular disease as men. Each year, about 461,200 women die from cardiovascular disease, compared with 410,400 men. At an AHA-sponsored meeting with reporters last month, Dr. Susan Bennett, director of the Women's Heart Program at George Washington University Hospital, Washington, said that while the death rate for men has declined 10% since 1979, it has stayed the same or increased for women. Dr. Bennett is leading the AHA effort to secure congressional passage of the HEART for Women Act, which had 189 sponsors in the last Congress. The bill will be reintroduced this month, according to the AHA.

Unique New Drugs on Decline

The Food and Drug Administration only approved 18 new molecular entities—including 4 biologics therapies and 4 new vaccines—last year, on par with the previous year, but close to a historic low. Throughout the 1980s and 1990s, the agency approved at least 20-30 NMEs annually. The paltry number of approvals and a Government Accountability Office report issued in December may point to a decline in new drug development, according to Rep. Henry Waxman (D-Calif.), Sen. Richard Durbin (D-Ill.), and Sen. Edward Kennedy (D-Mass.). The legislators requested the GAO report, which found that huge increases in drug industry research and development from 1993-2004 were not accompanied by a similar rise in new drug applications to the FDA. From 1993-2004, research and development spending increased 147%, while NME applications increased by only 7%. "These submission trends indicate that the productivity of research and development investments has declined," the GAO report said. Further, over the same period, FDA has continued to approve most submissions, but the number approved overall has declined.

Cardiac Cath Injection Code Added

The Centers for Medicare and Medicaid Services will now pay national rates for two cardiac catheterization injection codes, CPT 93539 and CPT 93540. The ACC and the Society for Cardiovascular Angiography and Interventions prevailed upon CMS to make an emergency update to the 2007 Medicare physician fee schedule. The two codes previously were priced by local Medicare carriers. Now they have been assigned relative value units, allowing them to be priced nationally, according to ACC. Local Medicare carriers can still price the technical component of the following injection codes, however: 93501, 93533, 93555, and 93556.

Part D Battle Begins in Congress

As promised during the midterm elections, House Democrats began work immediately on tweaking Medicare's Part D drug coverage. Rep. John Dingell (D-Mich.) along with 189 colleagues introduced H.R. 4, the Medicare Prescription Drug Price Negotiation Act of 2007, which would require the Health and Human Services department to negotiate prices with drugmakers. The legislation was passed by the House in January by a vote of 255-170. The Senate Finance Committee held hearings Jan. 11 to investigate the impact of price negotiations. If the legislation is enacted as currently written, new prices would go into effect for the plan year beginning Jan. 1, 2008.

FDA Panels Held Less Often

An advocacy group is charging that the FDA is holding outside advisory panel meetings less often than it did a decade ago. Public Citizen's Health Research Group analyzed the 275 advisory committee meetings held from 1997 to 2006. In 1998 and 1999, almost half of approved NMEs were preceded by panel meetings; from 2000 to 2006, only 24% (35) of the 147 NMEs approved had a committee meeting first, according to Public Citizen, which put its conclusions in a letter published in the Dec. 23 issue of the Lancet. The group also found that the FDA did not present its scientific opinion as a counterbalance to the drug maker's presentation at 18%, or 49 of the 275 meetings. The FDA overruled the panel conclusions 28% of the time, "a figure higher than is generally assumed," according to Public Citizen.

—Alicia Ault

Gainsharing Slowed by Hospitals' Legal Fears

BY MARY ELLEN SCHNEIDER
New York Bureau

Hospitals are reluctant to offer physicians a portion of the savings generated by reducing clinical costs—a concept known as gainsharing—because of legal worries, D. McCarty Thornton, said during an audioconference on gainsharing sponsored by the Integrated Healthcare Association.

"It's clear, I think, that gainsharing is not on the fast track," said Mr. Thornton, a partner with the law firm of Sonnenschein, Nath, and Rosenthal LLP, based in Washington.

In the long run, gainsharing approaches that can save money without impacting patient care are likely take hold, he said, but first hospitals need clarification from Congress, the Health and Human Services secretary, and the Office of Inspector General about what arrangements are allowed.

In 1999, the HHS Office of Inspector General issued a special advisory bulletin saying that the civil monetary penalty provision of the Social Security Act prohibits most gainsharing arrangements. Under that provision, hospitals are prohibited from making payments to physicians to reduce or limit services to Medicare and Medicaid beneficiaries. The bulletin said these types of arrangements could also trigger the antikickback provisions of the Social Security Act, which prohibit arrangements used to influence the referral of patients in federal health care programs.

"Historically, the office has been somewhat leery of gainsharing arrangements," said Catherine A. Martin, OIG senior counsel.

Since the 1999 bulletin, the OIG has issued several advisory opinions outlining gainsharing arrangements that would be allowable. In general, before giving the green light to a gainsharing arrangement, the OIG looks for transparency and accountability, quality of care controls, and safeguards against kickbacks, Ms. Martin said.

In order to be transparent, any actions taken to save costs need to be clearly and separately identified and fully disclosed to patients. Hospitals must also put in place controls to ensure that cost savings do not result in inappropriate reduction of services. OIG officials also want to see ongoing monitoring of quality by the hospital and an independent outside reviewer, Ms. Martin said.

But OIG is not the only regulator that hospitals and physicians need to consider when embarking on gainsharing arrangements, Ms. Martin said. Hospitals and physicians must also keep from running afoul of the Stark self-referral prohibitions, which fall under the purview of the Centers for Medicare and Medicaid Services. Gainsharing arrangements must also meet Internal Revenue Service rules, and hospitals are at risk for private lawsuits, she said. But the industry is keeping an eye on two demonstration projects that test the gainsharing concept in the Medicare fee-for-service program. Both projects are set to begin this year.

The first project, which is required under the Deficit Reduction Act of 2005, will involve 6 hospitals and will focus on quality and efficiency in inpatient episodes and during the 30-day postdischarge period. The DRA provision waives civil monetary penalty restrictions that would otherwise prohibit gainsharing.

The second project will focus on physician groups and integrated delivery systems and their affiliated hospitals. The demonstration will include inpatient episodes, as well as the pre- and posthospital care over the duration of the project. This demonstration was mandated by the Medicare Modernization Act of 2003.

Participants in both demonstrations will be required to standardize quality and efficiency improvement initiatives, internal cost savings measurement, and physician payment methodology, said Lisa R. Waters, a project officer with the division of payment policy demonstrations at CMS. ■