Policy & Practice

ACC Says Quality Is Job #1

The American College of Cardiology has launched a preemptive strike in the likely upcoming battle for health reform. The organization and 300 member-cardiologists spent a day last month lobbying Capitol Hill, armed with ACC's new QualityFirst campaign and evidence that cardiologists are already collecting quality data and crunching numbers to improve care. The QualityFirst campaign, which will be focused inside the Beltway, backs cost-effective, quality care; payment incentives; increased transparency; and coordination across care sites. "The current system and its focus on quantity, not quality, is unsustainable," said Dr. W. Douglas Weaver, ACC president, at a press briefing. The ACC also shared results of a poll of 1,003 likely voters conducted for the organization. Eighty-six percent of respondents said they'd trust physicians or medical or patient advocacy groups to set quality standards. In addition, 83% agreed that ACC's QualityFirst objectives were extremely or very important, and 64% said the organization's top priority should be setting new standards for health reform.

CMS Proposes Denial of CAS

The Centers for Medicare and Medicaid Services has proposed to keep the status quo—no coverage—of percutaneous transluminal angioplasty (PTA) of the carotid artery concurrent with stenting. The ACC, the Society for Vascular Medicine, and the Society of Vascular Interventional Neurology had asked the agency to reconsider and add coverage for patients who are at high risk for carotid endarterectomy because of defined anatomic factors, and who have symptomatic carotid artery stenosis of 50%-90% or greater or asymptomatic carotid artery stenosis of at least 80%. In comments on the proposed decision, the organizations again argued for coverage, citing "compelling scientific evidence" that revascularization prevents stroke, compared with medical therapy. "CMS should not require that CAS be superior to [carotid endarterectomy] to consider it a valid treatment option," according to the groups.

CMS Alters Overpayment Policy

CMS will no longer seek payment from a physician for an overpayment while the physician is seeking a reconsideration of the overpayment determination by a qualified independent contractor. Under the new policy, which was mandated by the 2003 Medicare Modernization Act, the agency can only seek to recoup the payment after a decision has been made on the reconsideration. The changes, which went into effect Sept. 29, apply to most Part A and Part B claims for which a demand letter has been issued. The changes do not affect the appeal process or the normal debt collection and referral process, according to the CMS.

PQRI Frustrating, But Not Costly

A total of 90% of physicians answering a Medical Group Management Association survey said that they had trouble accessing their confidential 2007 Physician Quality Reporting Initiative (PQRI) reports from the Centers for Medicare and Medicaid's secure Web site. Overall, 70% sought CMS help in getting the reports; of those, 11% rated the help as not satisfactory. The PQRI reports received average marks for clarity and slightly lower ratings for providing guidance on improving outcomes. Even so, 90% of the practices said they would participate in the 2008 PQRI program. Survey responses were taken from 295 practices who said they had reported on PQRI measures from July to December 2007. When asked why they participated, the largest weight was given to preparing for the future, when quality reporting is anticipated to play a bigger role in Medicare reimbursement. Overall, 61% of practices earned a bonus from 2007. Most practices said that participation had not led to the need for more staff or higher expenses.

—Alicia Ault

FDA Blocks Import of Ranbaxy Generic Drugs

BY ALICIA AULT
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The Food and Drug Administration said last month it would not allow generic drugs made by Ranbaxy Laboratories Ltd. at two of its Indian manufacturing plants to cross U.S. borders, citing an extensive history of manufacturing violations at those facilities.

According to the FDA the "import alert" covers 30 drugs made at Ranbaxy's Dewas and Paonta Sahib manufacturing plants, including simvastatin, fenofibrate, gabapentin, metformin HCl, ranitidine, and acyclovir.

Such a wide-ranging shutdown is not common for violations of "good manufacturing practices." But in a teleconference with reporters, Deborah M. Autor, director at the FDA's Center for Drug Evaluation and Research Office of Compliance, said the alert and two warnings letters were issued because of the seriousness of the manufacturing violations and the company's lack of quick and appropriate actions.

Consumers were advised not to discontinue any generic medication, even if it was manufactured by Ranbaxy, because of the agency's testing and the lack of adverse event reports relating to the products, said Douglas Throckmorton, deputy director of the CDER, in the teleconference.

The FDA began investigating in 2005 after it received reports of manufacturing violations and allegations of potential fraudulent activity at the Dewas and Paonta Sahib plants, said Ms. Autor. The agency documented significant violations of its good manufacturing practices (GMP) rules during inspections conducted in 2006.

Inspections of both plants early this year once again found significant violations. At the Dewas plant, the FDA cited the potential for cross-contamination from the facility's β-lactam manufacturing process, inadequate batch production and control records, inadequate failure investigations, and inadequate aseptic (sterile) processing operations.

The agency cited the Paonta Sahib plant for a lack of assurance that responsible individuals were present to determine the firm was following GMP rules, inaccurate written records of the cleaning and use of major equipment, incomplete batch production and control records, and inadequate procedures for the review and approval of production and control records.

Ranbaxy has also been under criminal investigation by the U.S. Department of Justice for alleged fraud relating to several of its FDA approvals. ■

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