

## **POLICY & PRACTICE**

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### **CMS Decision on Warfarin Test**

The Centers for Medicare and Medicaid Services has decided that evidence does not support coverage of pharmacogenomic testing to predict warfarin responsiveness in Medicare beneficiaries. The diagnostics test for the presence of the CYP2C9 or VKORC1 alleles. However, the agency said it would make the test available through its Coverage With Evidence Development authority, meaning that testing will be covered by Medicare for patients who have not been previously tested for the alleles, have been on warfarin for less then 5 days when the test is ordered, and are enrolled in a prospective, randomized, controlled study that meets certain CMS criteria. Those studies will gather evidence on the testing, and may "provide an opportunity ... to reconsider this determination," the agency said in its decision memorandum.

### **FDA Device Chief Resigns**

Dr. Daniel Schultz, the beleaguered director of the Food and Drug Administration's Center for Devices and Radiological Health, has resigned from the agency. According to *The Gray Sheet* (a sister publication to Cardiology News), Dr. Schultz submitted his resignation to Dr. Margaret Hamburg, FDA Commissioner, after they agreed that his departure "would be in the best interest of the center and the agency." The devices division has been under fire for about a year since whistleblowers from the division alleged corruption in a letter to Congress in 2008, and repeated many of

the charges in a January letter to President Obama. At press time, no replacement had been named for Dr. Schultz, who had directed the center since 2004.

### **Texas Heart Screening Law Signed**

Gov. Rick Perry (R) has signed a law requiring Texas insurers to pay for CT coronary artery calcium scans and carotid ultrasound scans that are used for atherosclerosis screening. The law took effect Sept. 1; insurers have to offer the coverage beginning with policies that renew in January, and must have the new coverage in place no later than September 2010. Insurers must pay a minimum of \$200 per covered individual every 5 years, and the coverage applies only to men aged 45-76 years, and women aged 55-76 years.

### **Lilly Payment Data Now Public**

Eli Lilly & Co. will publish how much it pays physicians and other health care professionals in consulting fees, honoraria, and the like. The drugmaker detailed the payments for the first quarter of 2009 at www.lillyfacultyregistry.com. The company said that it listed 3,400 people in the database. The average payment per service was \$1,000, and each professional conducted an average of six activities, according to Lilly. In September 2008, Lilly said it would voluntarily make physician payments public, but by February 2009, the company was required to do so as part of a Corporate Integrity Agreement with the federal government.

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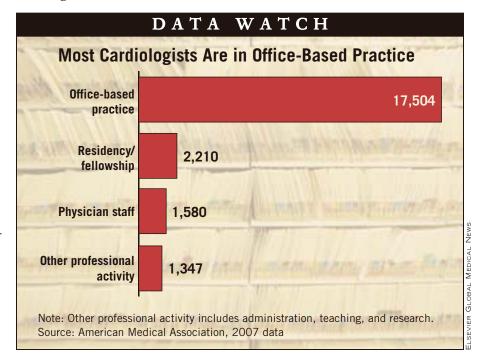
### **Bill Seeks Pay for Performance**

A small bipartisan group of senators has cosponsored legislation that would pay a physician for work under part of Medicare only if a patient's health status improves. Sen. Ron Wyden (D-Ore.), Sen. John Cornyn (R-Tex.), and Sen. Tom Harkin (D-Iowa) offered the Take Back Your Health Act of 2009 (S. 1640) to create a new Medicare program based on "comprehensive lifestyle programs." Such treatment plans would be designed by physicians specifically for each patient in the program. The plans can include nutritional therapy, exercise, medication management, care coordination, and tobacco-use cessation. Physicians wouldn't be paid if a patient were rehospitalized for a chronic illness accounted for in his or her plan. Sen. Wyden said in a statement that several trials of such a system, including those at Mutual of Omaha Insurance Co. and Highmark Blue Cross Blue Shield, have shown that comprehensive lifestyle programs can result in up to 50% reductions in medical costs.

### **Faulty Off-Label Prescribing?**

A survey of 250 physicians—135 psychiatrists and 115 primary care doctors—found that many lack knowledge of certain drugs' approved indications. The study was published online in Pharmacoepidemiology and Drug Safety (doi: 10.1002/pds.1825). A large minority of physicians were mistaken that drugs were approved for uses they prescribed. For instance, 33% of respondents said they had prescribed lorazepam for chronic anxiety believing that it was approved for that, but the FDA warns against that use. Psychiatrists tended to be more accurate than primary care physicians.

—Alicia Ault



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