# POLICY & PRACTICE

### Vermont Bans Most Pharma Gifts

Vermont Gov. Jim Douglas (R) has signed into law a bill that prohibits manufacturers of drugs, medical devices, and biologics from providing free gifts, including meals and travel, to physicians and other health care providers. The legislation, which is the toughest of its kind in the nation, also requires disclosure of any allowed gifts or payments, regardless of their value. In 2002, a Vermont law required disclosure of gifts or payments of $25 or more. Under the stronger law, manufacturers can give physicians only gifts such as samples intended for patients, "reasonable quantities" of medical device evaluation or demonstration units, and copies of peer-reviewed articles. The companies still can provide scholarships or other support for medical students, residents, and fellows to attend educational events held by professional associations, as long as the association selects the scholarship recipient.

### Obama: Give MedPAC More Clout

President Obama's administration wants to give the Medicare Payment Advisory Commission greater influence. In a June 2 letter to Sen. Ted Kennedy (D-Mass.) and Sen. Max Baucus (D-Mont.), President Obama said he supported giving each MedPAC recommendation the force of law unless it is opposed by a joint resolution of Congress. This appeared to embrace the approach in the MedPAC Reform Act of 2009, which Sen. Jay Rockefeller (D-W.Va.) introduced in May. Currently, MedPAC advises Congress, which then decides whether to act on the recommendations. At a Brookings Institution conference in mid-June, White House Office of Management and Budget Director Peter Orszag reiterated support for giving MedPAC more teeth. Mr. Orszag said the administration wanted to "take the MedPAC recommendations and, rather than having them sit on a shelf somewhere, have them protected in a fast track procedure, voted up or down as a package, and considered within a limited period of time so they become much more relevant."

### ED Overcrowding Continues

The emergency department wait time to see a physician for emergent patients—those who should be seen in 1-14 minutes—averaged 37 minutes in 2006. Half of such patients waited longer than recommended, the Government Accountability Office said in a report. In addition, patients who should have been seen immediately waited an average of 28 minutes, and about three-fourths had to wait to be seen. Hospitals performed better with urgent cases: Those patients, who should be seen in 15-60 minutes, waited an average of 50 minutes, and about 20% waited longer than recommended, the report indicated. Lack of inpatient beds continues to be the main driver of emergency department overcrowding. ED boarding of patients who are waiting for an inpatient bed continues to be a problem, the GAO noted. The American College of Emergency Physicians warned that overcrowding and wait times will only get worse as the population ages. "People age 65 and older represent the fastest growing segment of the population and the group whose visits to the emergency department are increasing the fastest," Dr. Nicholas Jouriles, president of ACEP, indicated in a statement.

### Crossover Claims Investigated

Reports that crossover claims from Medicare to Medicaid are not being automatically filed in several states are being examined by the Physicians Regulatory Issues Team. The PRIT works with health care providers to address Medicare payment issues. According to Dr. William Rogers, director, the Healthcare Billing and Management Association and the Medical Group Management Association have been receiving complaints from members alleging that crossover claims from Medicare to Medicaid are not automatically being completed, as they should be. And "if you have to handle any paperwork to bill Medicaid for the copay, you've already burned up any revenue you might have generated" from the Medicaid claim, said Dr. Rogers. The states under investigation include New York, North Carolina, Louisiana, Nevada, South Carolina, Georgia, Kentucky, and Texas. Dr. Rogers said that physicians who believe their state Medicaid program is not accepting automatic crossover claims from Medicare should contact the Medical Group Management Association or Healthcare Billing and Management Asssociation, or e-mail Dr. Rogers at wrogers@cms.hhs.gov.

**—Alicia Ault**


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# CMS Not Inclined to Cover Genetic Test for Warfarin

BY ALICIA AULT

There is not enough evidence to support coverage of pharmacogenomic testing that predicts a patient's response to warfarin, the Centers for Medicare and Medicaid Services announced in May.

The testing can be covered if it is part of a prospective, randomized trial that meets certain criteria proposed by the agency, said the CMS, which opened a 30-day comment period on the proposal.

In particular, the study should determine whether the test can predict the frequency and severity of major and minor hemorrhage, thromboembolism related to the primary indication for anticoagulation, other thromboembolic events, and mortality, the agency noted. In addition, any such trial should determine whether the results are generalizable to the Medicare population.

There are a number of lab tests already approved by the Food and Drug Administration, and many labs offer so-called "home-brew" tests.

Although there is evidence to indicate that these tests accurately identify people with certain gene variants that might heighten their responsiveness to warfarin, there is not any direct evidence of any improvement in health as a result, the agency indicated in its proposed decision.

The CMS proposal is not much of a surprise. In February, a Medicare Evidence Development and Coverage Advisory Committee determined that there were not enough data to support national coverage of the testing. The panel suggested that the data be compiled from a Coverage with Evidence Development study, which the CMS suggested in its proposed decision.

In comments to the CMS, there was a split of opinion among various professional societies.

The American Association for Clinical Chemistry and the College of American Pathologists supported coverage.

The American Society of Hematology, American College of Chest Physicians, and American College of Medical Genetics said there was not sufficient evidence at the moment.

The agency said it is possible that trials will show genetic testing to be of benefit.

"The ability to more effectively treat or prevent blood thrombosis and avoid the risk of hemorrhage due to overanticoagulation by guiding warfarin dosing based on genetic testing results would be a worthwhile potential benefit for the numerous Medicare beneficiaries, perhaps exceeding one million annually, who are initiating anticoagulant therapy," the agency noted in its decision. ■