

POLICY & PRACTICE

CMS Urged to Improve Efficiency

Medicare patients who see an "outlier generalist," a physician who treats a disproportionate share of overly expensive patients, were more likely to have been hospitalized, more likely to have been hospitalized multiple times, and more likely to have used home health services than were other Medicare patients, the Government Accountability Office found in a report. Based on those findings, the GAO recommended that the Centers for Medicare and Medicaid Services develop a system that identifies individual physicians with inefficient practice patterns and uses the results to improve the efficiency of care in the Medicare system. Although CMS has discussed only using profiling results for educating physicians, the optimal system, according to the GAO, would include financial or other incentives to encourage efficiency.

Overcrowded Hospitals Riskier?

Hospitals that operate at or over their capacity might be at increased risk of adverse events that injure patients, according to a study led by investigators from Massachusetts General Hospital (MGH) and Brigham and Women's Hospital, both in Boston. The report in the May issue of the journal *Medical Care* suggests that efforts to reduce costs and improve patient safety might work against each other. The researchers reviewed data from four hospitals in two states over 12 months and identified 1,530 preventable injuries not resulting from patients' underlying medical conditions. At three of the four hospitals, the rate of adverse events did not appear to increase at times of peak workload. But at the fourth—a major urban teaching hospital with consistently high occupancy rates that exceeded 100% for more than 3 months—workload increases and higher patient-to-nurse ratios were associated with more adverse events. "Our study suggests that pushing efficiency efforts to their limits could be a double-edged sword that may jeopardize patient safety," said study lead author Dr. Joel Weissman of the MGH Institute of Public Policy in a statement.

N.H. Rx Law Struck Down

A federal judge in New Hampshire has struck down a state law banning commercial use of provider-identifiable prescription information, finding that it "unconstitutionally restricted speech." Judge Paul Barbadoro ruled in favor of health information companies IMS Health and Verispan LLC, which jointly filed a lawsuit seeking to prevent the state from enforcing the statute, which went into effect last June. The law was the first in the nation to ban the commercial use of information on what medications individual physicians prescribe. New Hampshire argued that the law aimed to protect physicians' privacy, end inappropriate pharmaceutical marketing, and cut costs. The plaintiffs said that using physicians' prescription data is crucial to improving quality. "The free flow of health care information is central to ev-

idence-based medicine and improved patient outcomes," said IMS vice president Randolph Frankel in a statement.

IT Bill Would Aid Small Practices

Seeking to help physicians who might like to adopt health information technology (HIT) systems but cannot afford the investment, Reps. Charlie Gonzalez (D-Tex.) and Phil Gingrey (R-Ga.) have introduced legislation that would provide grants, loans, and tax incentives to small practices that implement computer systems. The bill is designed to facilitate the development and adoption of national standards, and to provide initial financial support and ongoing reimbursement incentives for physicians in smaller practices to adopt HIT to support quality improvement activities. The legislation is based in large part on ideas originally developed by the American College of Physicians (ACP), the physicians' group said. Studies have estimated that an electronic health records system averages \$44,000 per physician initially, and \$8,500 per physician annually to maintain. "The proposed financial incentives would make it possible for physicians in small practices to invest in the technology and encourage its continued use to improve patient care," said Dr. Lynne Kirk, ACP president.

Debridement Restrictions Lifted

The American Academy of Family Physicians (AAFP) said it has succeeded in its drive to remove restrictive language from a Medicare carrier's draft local coverage determination on wound care. The restriction would have affected physicians in Delaware, Maryland, Texas, and Virginia. Last December, AAFP questioned TrailBlazer Health Enterprises' proposed debridement limits of three times for one wound. AAFP said that although repetitive debridement of one wound is uncommon, sometimes serial debridement is the only option. TrailBlazer removed the restrictions from its final policy, released in April.

Adults Disregard MDs' Orders

In a recent survey, 44% of U.S. adults said that they or an immediate family member have ignored a doctor's course of treatment or sought a second opinion because they felt the doctor's orders were unnecessary or overly aggressive. Most adults reported that they didn't view disregarding a doctor's recommendations as problematic or consequential. Only 1 in 10 adults who chose to disregard a physician's instructions at some time believes that he or she or a family member experienced problems because of this decision, with the most common consequence being lost time from work or school. The survey, conducted by Harris Interactive for the Wall Street Journal Online's health industry edition, also found that a large majority of adults think patients who have medical conditions often experience problems because of overtreatment as well as undertreatment by medical providers.

—Jane Anderson

Medicare Nixes Expanded Coverage of Carotid Stents

BY MARY ELLEN SCHNEIDER
New York Bureau

Officials at the Centers for Medicare and Medicaid Services have reversed a proposal to expand coverage for carotid artery stenting in asymptomatic patients.

Instead, Medicare will continue to cover percutaneous transluminal angioplasty of the carotid artery concurrent with stenting, mainly in patients who are at high risk for carotid endarterectomy (CEA) and who also have symptomatic carotid artery stenosis of 70% or greater.

Medicare also will continue to cover the procedure in patients at high risk for CEA with symptomatic carotid artery stenosis between 50% and 70% in Category B Investigational Device Exemption (IDE) trials and in postapproval studies. The procedure will be covered only in asymptomatic patients under limited circumstances. Medicare will cover patients who are at high risk for CEA and have asymptomatic carotid artery stenosis of 80% or greater as part of a Category B IDE trial or a postapproval study.

The proposed decision to expand coverage of carotid artery stenting in asymptomatic patients outside of the protection of clinical trials and postapproval studies was "premature," CMS said in its decision memo. However, officials also noted that registry and postapproval studies show a trend toward improving outcomes, and so they have continued coverage for patients who are enrolled in clinical trials or are part of postapproval studies.

Reversals of CMS-proposed coverage decisions are rare, a CMS spokesman said.

The policy reversal means that the agency will not proceed with plans to restrict coverage for patients 80 years of age or older to clinical trials and postapproval studies. And CMS also will not go forward with its proposal to require a surgeon to perform a consultation to ascertain a patient's high-risk status before undergoing carotid artery stenting (INTERNAL MEDICINE NEWS, March 1, 2007, p. 27).

Although CMS has rolled back most of the provisions of its February 2007 carotid artery stenting proposal, some aspects will remain in place. For example, CMS plans to implement the clarifications regarding embolic protection devices and the facility certification and recertification process.

Under the coverage decision, carotid artery stenting is covered only when used with an embolic protection device. The procedure will not be covered if the deployment of the distal embolic protection device is not possible.

Overall, the CMS coverage demo is fair and evidence based, said Dr. Eric R. Bates, a cardiologist and professor of internal medicine at the University of Michigan in Ann Arbor. "Everybody gets a little something out of it," he said.

The decision not to expand coverage to asymptomatic patients makes sense and is based on the available evidence, he said. However, since it continues to cover the

procedure in clinical trials and postapproval studies, it still leaves the door open for improvements in the technology, case selection, and operator skills, he said.

"I don't think you can be too critical of the decision," Dr. Bates said.

But although CMS has done a good job of requiring evidence before expanding coverage, Dr. Bates said he is concerned that too many hospitals have been approved to perform carotid artery stenting for high-risk patients. Currently, 1,057 hospitals have met CMS minimum facility standards to perform the procedure in high-risk patients.

The coverage decision reversal is good news in the eyes of many in the neurology community who had urged CMS officials to be cautious in expanding coverage in this area. Both the American Academy of Neurology and the American Association of Neurological Surgeons submitted comments to CMS in which they said that available evidence did not warrant expansion.

The groups noted that the CMS proposal was based on case series data and company registries, which can be biased and are not helpful in determining efficacy.

In comments to the agency, officials at AANS recommended that CMS review its policies regarding carotid endarterectomy in high-risk asymptomatic patients. Both carotid artery stenting and CEA should be evaluated among those patients in a randomized clinical trial statistically powered to determine efficacy, AANS said.

"There is insufficient evidence regarding the relative risk of [carotid artery stenting] versus CEA in all asymptomatic high-risk subgroups to suggest that either procedure is superior to best medical therapy," AANS wrote in comments to CMS. "Accordingly, it would be inappropriate and not in the best interest of patient care to change the [carotid artery stenting National Coverage Determination] to include asymptomatic high-risk patients in any age group at this time."

Efforts to expand coverage now would make the development and completion of a randomized trial comparing CEA, carotid artery stenting, and medical therapy difficult, if not impossible, the American Stroke Association said in comments to CMS.

However, in comments to CMS, the American College of Cardiology and the Society for Cardiovascular Angiography and Interventions supported efforts to expand carotid artery stenting to asymptomatic patients at high risk for CEA.

Expanded coverage was requested in March 2006 by Abbott Laboratories, which manufactures two carotid artery stent products, based on new evidence, including four Abbott-sponsored studies.

"This is a disappointing decision for carotid artery disease patients who are at high risk for surgery and who don't have symptoms of stroke," the company said in a statement. "However, these patients will still have access to carotid artery stenting as a treatment option if they are enrolled in FDA-approved postmarketing clinical trials." ■