

speak with their health care provider.

The long delay between the approval of Budeprion XL 300 mg in late 2006 and the appearance of the bioequivalence results reported here, during which the product remained listed by the FDA as a generic substitute for Wellbutrin XL 300 mg, is problematic. Because of the risk of seizure associated with high doses of bupropion, the agency initially took a conservative approach to trial design. Today, the FDA has greater understanding of the risk of seizure with bupropion. At the time of the sponsor's 2007 study, some critics considered its design to be flawed. The results of the recent study by the FDA show that a design entailing the enrollment of a more accessible trial population might well have brought the bioequivalence data to light sooner. In retrospect, the conservative approach did not

provide the right conclusions regarding therapeutic equivalence in a timely manner.

We do not believe that the results of the FDA study should cause concern regarding the overall reliability of the agency's approval process for generic drugs, including the use of extrapolation, when scientifically appropriate. Technical aspects of the Budeprion formulation may have led to the failure of extrapolation in this case. More information on this issue will be generated by the other sponsors' bioequivalence studies. The other 300-mg generic bupropion products do not use the same technology as Budeprion. The use of extrapolation for the approval of multiple strengths of generic drugs, which incorporates science-based reasoning, has been generally successful, and the FDA will continue to refine its approach to this method. The agency will also

move more aggressively to perform its own studies when data are urgently needed. We wish to assure the public that drug products that are approved for generic use will continue to be held to high standards of quality, safety, and efficacy.

Disclosure forms provided by the authors are available with the full text of this article at NEJM.org.

From the Center for Drug Evaluation and Research, Food and Drug Administration, Rockville, MD.

This article was published on December 5, 2012, at NEJM.org.

1. Guidance for industry: bioavailability and bioequivalence studies for orally administered drug products — general considerations. Washington, DC: Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research (CDER), 2003 (<http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM070124.pdf>).

DOI: 10.1056/NEJMp1212969

Copyright © 2012 Massachusetts Medical Society.

## Higher-Complexity ED Billing Codes — Sicker Patients, More Intensive Practice, or Improper Payments?

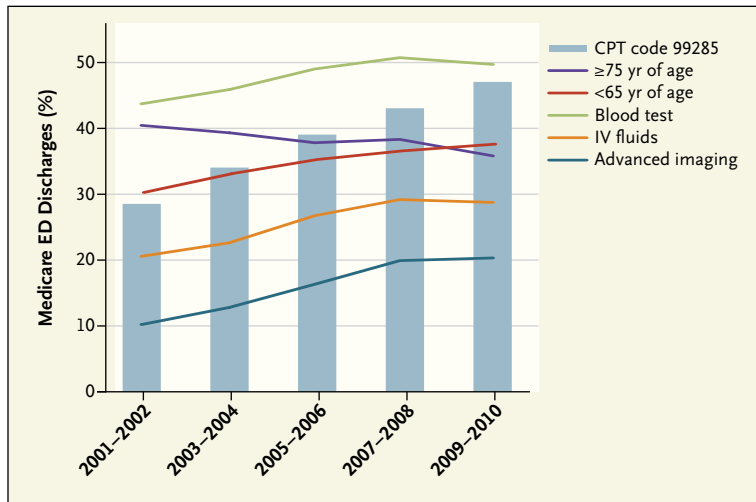
Stephen R. Pitts, M.D., M.P.H.

A recent analysis of Medicare billing data for evaluation-and-management services, conducted by the Office of Inspector General (OIG) of the Department of Health and Human Services, showed that between 2001 and 2010, the proportion of claims for lower reimbursement categories decreased while the use of higher-paid categories increased across all visit types.<sup>1</sup> The largest increase reported was in level 5 emergency department (ED) visits (Current Procedural Terminology [CPT] code 99285; average reimbursement, \$173) — from 27% to 48% of Medicare discharges (see graph).

Although the report didn't assess the reasons for higher billing levels, its findings have been amplified by investigative reports in the media suggesting that fraud is the cause. On September 24, 2012, a formal letter from the U.S. Departments of Justice and Health and Human Services to hospital leaders warned of an escalated effort to prevent fraud and abuse and explicitly linked higher bills to "gaming" made possible by new electronic health record (EHR) technology. The OIG report addressed only physician billing, not hospital billing, and the office has initiated further study into usage of all CPT

codes. Although it's possible that "up-coding" facilitated by increasing use of EHRs has contributed to the trend, other causes such as changing demographics, shifting practice patterns, and the ED's evolving role in the health care system must also be considered.

To explore these potential contributors, I analyzed a nationally representative sample of Medicare ED discharges in the National Hospital Ambulatory Medical Care Surveys, using methods described previously and detailed in the Supplementary Appendix (available with the full text of this article at NEJM.org).<sup>2</sup> Like the OIG report, my analysis excludes the 35% of



**Changes in Use of the Billing Code for Level 5 ED Visits, in the Age Range of Medicare Patients Discharged from the ED, and in the Use of Diagnostic Technology and IV Fluids, 2001–2010.**

Lines represent estimates from the public-use files of the National Hospital Ambulatory Medical Care Survey, excluding the 2010 estimates, which were not available. The average sample of Medicare discharges was 3747. All slopes are statistically nonzero at  $P < 0.01$  in logistic-regression models, with survey years defined as a continuous variable. CPT denotes Current Procedural Terminology.

Medicare ED visits that lead to hospitalization or transfer.

Between 2001 and 2009, the average age among all patients discharged from the ED increased by 0.18 years annually, but among Medicare patients discharged from the ED, the mean age trended downward (see graph). In 2006, 38% of these Medicare patients were younger than 65 years, whereas only 19% of the total Medicare population was in that age group. The disposition of Medicare patients under 65 after an ED visit is often more difficult than that of older Medicare patients, because on average, such patients have worse self-reported health status and are more likely to be disabled, poor, or cognitively impaired.<sup>3</sup> In 2006, 33% of Medicare patients under 65 who were discharged from the ED were in the costly “dual eligible” category also covered by Medicaid, whereas only 21% of all Medicare beneficiaries were dual eligibles.

Along with demographic chang-

es in the Medicare ED population, the overall health care system and the ED's role in medical care changed sharply during the decade of the OIG study. The marked increase in use of new diagnostic technology in U.S. medicine was magnified in the ED, with its ready access to hospital-based advanced imaging: computed tomography (CT), magnetic resonance imaging, and ultrasonography (see graph). In the past decade, an increasingly strained primary care infrastructure for adults has resulted in greater use of the ED for first-contact care.<sup>4</sup> Lack of stable “medical homes” encourages ED physicians to seek greater diagnostic certainty before discharging a patient. The three most common symptoms reported by Medicare patients who are ultimately discharged from the ED are abdominal pain, chest pain, and shortness of breath — all challenging diagnostic problems that often necessitate testing that's unavailable in office set-

tings, in order to diagnose serious conditions. For example, technological innovations have revolutionized care for abdominal pain. Whereas surgical consultation and hospitalization were once standard, multidetector CT now permits rapid risk stratification in the ED, often averting the need for admission or consultation for patients with negative tests. The diagnostic precision afforded by these technologies is increasingly expected by patients, physicians, and the public. Failure to diagnose patients' conditions carries heavy penalties for ED physicians and hospitals, whereas “overuse” of technology is ill defined, and penalties for it are less direct.

The ED has also been affected by another major trend: hospitals' reduced inpatient capacity has led to widespread boarding of inpatients in ED hallways. This trend contributes to shifting of work formerly done in inpatient wards to the ED, encouraging EDs to discharge patients with borderline health status (who might have been admitted in the past) in order to reduce crowding and prolonged waits.

The result of these changes is an increasingly interventionist ED practice style, illustrated not only by increased imaging, but also by increased laboratory testing and initiation of IV fluids (see graph). Whether this trend has truly improved patient safety and quality of care is unknown, but it has certainly increased the complexity of the medical decision-making component of documentation, which translates into higher physician billing.

Finally, the culture of billing for medical services changed with the implementation of evaluation-and-management guidelines in the late 1990s. Physicians have

adapted: some have become students of the coding procedures, but many have outsourced billing to professional coders trained to search for keywords. Although many ED physicians don't know exactly what is billed in their name, physicians commonly receive regular feedback on their average billing performance through automated reports.

Early adoption of electronic records by the ED may in part explain the sharper billing increases in emergency medicine than in other clinical specialties. The EHR facilitates billing by presenting clickable check-boxes that easily satisfy coding-complexity criteria, and some EHRs even issue notifications when documentation needed for certain billing levels has not been achieved. These changes ensure that no billable action goes unnoticed and have reduced undercoding. In fact, EHR vendors tout this effect to justify the cost of their products. In other ways, however, the EHR has become a double-edged sword, potentially undermining its intended goal of reducing medical errors. Throughput suffers when time that could be better spent with patients is wasted on elaborate documentation. The EHR may also facilitate improper behavior, such as clicking multiple items in the "review of systems" that patients were not directly asked about. Of even

greater concern is the possibility of deliberate, systematic use of easily selected templates designed to ensure billing at the highest possible level, rather than promoting validated clinical decision rules and protocols designed to improve efficiency and quality. Although ED physicians are increasingly employed by hospitals, hospital chains, or contract groups with productivity-based compensation,<sup>5</sup> the OIG holds individual physicians accountable for billing done in their name, regardless of who directly manages the billing operations.

What should be done about the trend in billing? A first step is to do what the OIG report proposes: educate physicians about the importance of proper billing, review billing records to ensure that results match performance, and scrutinize physicians who consistently bill at higher levels than their peers.<sup>1</sup> From a broader perspective, the science of ED operations should be advanced to facilitate timely care. These advances should include the development of a more effective business model for the digital era that allows ED practitioners to get away from the computer and back to the bedside of sick and injured patients.

The EHR is one reason behind increased ED billing, and fraud may be facilitated by these new systems. However, this simple ex-

planation does not capture the broader story of what happened in U.S. EDs during the decade the OIG examined. While the ED has remained the social safety net, it has also gradually inherited roles previously handled by office-based physicians. EDs have become a central staging area for acutely ill patients, for the use of diagnostic technology, and for decisions about hospital admission, all of which makes ED care increasingly complex.

Disclosure forms provided by the author are available with the full text of this article at [nejm.org](http://nejm.org).

From the Department of Emergency Medicine, Emory University School of Medicine, Atlanta.

1. Department of Health and Human Services, Office of Inspector General. Coding trends of Medicare Evaluation and Management Services. May 2012 (<http://oig.hhs.gov/oei/reports/oei-04-10-00180.pdf>).
2. Pitts SR, Pines JM, Handrigan MT, Kellermann AL. National trends in emergency department occupancy, 2001 to 2008: effect of inpatient admissions versus emergency department practice intensity. *Ann Emerg Med* 2012;60:679-86.
3. Cubanski J, Huang J, D'Amico A, Jacobsen G, Neuman T. Medicare chartbook. 4th ed. Washington, DC: Kaiser Family Foundation, 2010 (<http://www.kff.org/medicare/8103.cfm>).
4. Pitts SR, Carrier ER, Rich EC, Kellermann AL. Where Americans get acute care: increasingly, it's not at their doctor's office. *Health Aff (Millwood)* 2010;29:1620-9.
5. O'Malley AS, Bond AM, Berenson RA. Issue brief no. 136: rising hospital employment of physicians: better quality, higher costs? Washington, DC: Center for Studying Health System Change, August 2011:1-4 (<http://www.hschange.com/CONTENT/1230>).

DOI: 10.1056/NEJMp1211315

Copyright © 2012 Massachusetts Medical Society.

## Appropriateness Criteria and Elective Procedures — Total Joint Arthroplasty

Hassan M.K. Ghomrawi, Ph.D., M.P.H., Bruce R. Schackman, Ph.D., and Alvin I. Mushlin, M.D.

Many of the most common inpatient surgeries in the United States are elective procedures. With health insurance cov-

erage expanding under the Affordable Care Act, utilization of elective surgery is likely to increase — with implications for

costs and the expansion of capacity required to meet the new demand and achieve good outcomes.