POLICY & PRACTICE

Bill Sets DXA, VFA Payment Floor

Endocrinologists, ob.gyns., and other physicians support new federal legislation that would establish a payment floor for dual-energy x-ray absorptiometry (DXA) and vertebral fracture assessment (VFA). The Medicare Fracture Prevention and Osteoporosis Testing Act of 2009 (S. 769, H.R. 1894), would set a national minimum payment amount for DXA (CPT code 77080) and VFA (77082) that could not be less than the 2006 Medicare payment rates for these services. If enacted, the payment rates would go into effect Jan. 1, 2010. The legislation also directs the Institute of Medicine to study the impact of Medicare payment reductions for DXA and VFA on beneficiary access to bone mass measurement and quality of care. The legislation would counteract deep Medicare payment cuts that began in 2007 under the Deficit Reduction Act. The new bill is supported by the DXA Task Force, which includes the American Association of Clinical Endocrinologists, the American College of Obstetricians and Gynecologists, the American College of Rheumatology, and other physician groups.

Americans Fear Chronic Disease

More than half of Americans say that developing a chronic illness would be worse than amassing considerable financial debt, getting divorced or living alone, or losing one's job, according to an online survey of more than 2,500 people conducted by Harris Interactive. About half of respondents had not spoken with their physicians about common chronic illnesses such as heart disease, cancer, diabetes, HIV/AIDS, or Alzheimer's, the survey found. Although 83% of respondents knew that being overweight or obese was a risk factor for diabetes, 67% said they had a poor diet and 62% said they maintained an unhealthy weight. "These people are gambling daily by ignoring risk factors for a life-altering disease like diabetes and doing nothing about it," said Dr. Richard M. Bergenstal, president-elect for medicine and science at the American Diabetes Association, which jointly funded the study with the WellPoint Foundation.

EHR Applications Rise

By a March 31 deadline, 64 companies applied for certification of their electronic health record (EHR) products, one-third more than the number that applied by the same time last year, the Certification Commission for Healthcare Information Technology reported. Nearly 40% of the applications were for new EHR products, according to the federally recognized commission. The biggest category of applications was for EMR products concerning health records for children.

FDA Warns on Internet Ads

The Food and Drug Administration has warned 14 drug makers against using brief Internet ads that are misleading because they fail to provide full information about risks and indications. The ads typically appear on search engines as "sponsored links" when patients search for information on medical conditions. The ads cited by the FDA include promotions for diabetes treatment Avandia (rosiglitazone), multiple sclerosis drug Tysabri (natalizumab), and the cardiovascular drug Plavix (clopidogrel). The sponsored links generally contain about a dozen words—not enough to convey detailed treatment or risk information, the FDA said. The Pew Prescription Project, a nonprofit drug-safety group, has asked the FDA to articulate the rules regulating online advertising and to advise manufacturers on where risk disclosures may appear in Internet ads.

New Ethics Rules at Johns Hopkins

Johns Hopkins University has joined the growing ranks of medical schools that are restricting interactions with pharmaceutical companies. The new Johns Hopkins Medicine Policy on Interaction With Industry, which takes effect July 1, prohibits acceptance of gifts or entertainment, regardless of value, from pharmaceutical and medical device companies. Consulting contracts that include no actual duties also will be prohibited. Starting in 2010, Johns Hopkins will no longer accept free pharmaceutical samples, but in some limited cases, deidentified samples may be used for patient education. "This policy will help us promote a culture in which Hopkins faculty and other personnel can exercise independent, unbiased judgment in all their activities while interacting with industry in appropriate ways that support our missions of delivering excellent care to patients, and integrity in teaching and research," said Edward D. Miller, dean of the medical faculty and CEO of Johns Hopkins Medicine.

Administration Posts Filling Up

The Obama administration has named officials to several top health care–related positions that do not require Senate confirmation, including the director of the White House Office of Health Reform, administrator of the Health Resources and Services Administration, and the new National Coordinator for Health Information Technology. Nancy-Ann DeParle, who ran Medicaid and Medicare under President Clinton, will lead the White House office. Rural health expert Mary Wakefield, Ph.D., R.N., was selected to head HRSA, joining the agency from the University of North Dakota, Grand Forks. Internist David Blumenthal, former director of the Institute for Health Policy at Massachusetts General Hospital, Boston, will take the lead on creating a nationwide health information technology infrastructure. Three new members will join the U.S. Preventive Services Task Force: Susan Curry, Ph.D., of Iowa City, an expert on tobacco use; Dr. Joy Melnikow of Sacramento, a family physician; and Dr. Wanda Nicholson of Baltimore, a board-certified ob.gyn. and a perinatal epidemiologist.

—Joyce Frieden

BUSINESS BRIEFS

GE, Intel Form Alliance

GE and Intel Corporation are forming an alliance to develop products to help elderly patients manage their chronic illnesses, the companies announced. They will invest $250 million over the next 5 years for research and development of home health technologies in areas such as diabetes, cardiovascular disease, medication compliance, and sleep apnea. The market for telehealth and home health monitoring is predicted to grow from $3 billion in 2009 to an estimated $7.7 billion by 2012. GE Healthcare also will sell and market the Intel Health Guide, a personal health system that includes vital sign collection and communication tools, in the United States. "This partnership offers the potential to lower costs by keeping people out of hospitals while giving health professionals the data they need to deliver the best possible care," Jeff Immelt, GE's board chairman and CEO, said in a statement.

Immuron Buys Hasadit's Technology

Immuron, a biopharmaceutical company, has agreed to acquire a novel oral immune modulation technology from Hadasit, the commercial arm of Hadassah Medical Center in Jerusalem. The combination of oral immune modulation with Immuron's existing oral protein and antibody technology could yield "a convenient, all-natural, side effect–free approach to address serious diseases which have multibillion-dollar markets, including metabolic syndrome, hepatitis C, and type 2 diabetes," the company said in a statement. Immuron will focus its initial clinical development effort with this platform technology on metabolic syndrome, chronic hepatitis C, and liver cancer. Hadasit also will provide discounted clinical and laboratory services to Immuron. In return, Hadasit shall be issued 19.99% of Immuron's equity at the time of the approval of the transaction by Immuron's shareholders, as well as royalties on certain Immuron products. Professor Yaron Ilan of Hadassah Medical Center will become the medical director of Immuron.

Quest Pays Government $302 Million

Quest Diagnostics will pay the government $302 million to settle False Claim Act allegations that a former subsidiary knowingly sold a parathyroid hormone test kit with inaccurate performance claims, the Justice Department reported. The investigation was initiated by a whistleblower lawsuit filed by a Quest competitor in 2004. The payout is one of the largest recoveries in a case involving a medical device, according to the Justice Department. "This settlement provides further evidence that the department will vigorously prosecute cases involving violations of the Food, Drug, and Cosmetic Act, and will pursue recovery of taxpayer dollars resulting from fraudulent marketing campaigns by medical device manufacturers," said Michael F. Hertz, acting assistant attorney general for the civil division.

Novocell Receives Endoderm Patent

Novocell Inc., a stem cell engineering company, has received a patent for its work with human definitive endoderm cells, an essential cell for generating pancreatic-type cells and other endoderm lineage–derived tissues and organs, including lung, intestine, liver, thymus, and thyroid cells. Novocell is developing pancreatic-type cells for use in diabetes therapy. "This composition patent is a milestone achievement for Novocell and is the culmination of extensive research that opened the door to the endoderm lineage," said Fred Middleton, Novocell's chairman and acting CEO. "The efficient production of endoderm represents the first critical step in the creation of a renewable islet source derived from [human embryonic stem] cells that is targeted at restoring normal glucose regulation in diabetic patients."

Biodel Plans VIAject NDA

Biodel Inc. plans to submit a new drug application to the Food and Drug Administration for approval to market its VIAject ultrarapid-acting injectable human insulin for the treatment of diabetes, the company announced last month. VIAject is intended for mealtime use by type 1 or type 2 diabetes patients. The NDA will be based upon results from multiple pharmacokinetic and pharmacodynamic studies as well as two completed phase III studies. Now that the company has cleared up some issues surrounding patient data from India, "We are … comfortable proceeding with the preparation and submission of the NDA for VIAject in the second half of this year," said Solomon Steiner, Ph.D., Biodel's chairman and CEO. "This is based on a compelling package of pharmacodynamic studies demonstrating potential advantages over currently available rapid-acting insulin analogs as well as the results of both pivotal phase III clinical trials, which we believe met the end point of noninferior change in HbA_{1c} over 6 months."

—From staff reports

Reporters and editors from Elsevier's "The Pink Sheet" contributed to this column.

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