Policy & Practice

Diabetes Management at Chrysler

A pilot program designed to improve the health of Chrysler employees with diabetes has been deemed a success. The company enrolled 126 employees in its Auburn, Mich., headquarters in the program, which consisted of individual coaching sessions with certified diabetes educators. More than three-quarters of enrollees completed at least four coaching sessions. After 6 months, 77% of enrollees had reduced their HbA_{1c} level to less than 7%. At the program's start, 68% had HbA_{1c} levels at or below 7%. Participants' cholesterol levels improved slightly, with 42% having LDL cholesterol values less than 100 mg/dL at the program's end, compared with 39.5% at the study's start. Knowledge of diabetes and its management improved by more than 18%. "We love the direction this program is taking us," said Cyndy Parker, Chrysler's healthy people initiatives manager. No word yet on whether the program saved money.

Part D Formulary Override Form

A new one-page form allows physicians to request a prior authorization or coverage of a nonformulary drug under Medicare Part D. The form can "easily communicate to drug plans why a patient needs a specific drug when similar drugs are covered by the plan," American Medical Association board member Dr. Edward Langston said in a statement. AMA led a coalition of groups that developed the form. The form, which is used to explain the need for an alternative drug or dose, or why the formulary drug is not acceptable, is available at the Centers for Medicare and Medicaid Services' site: http://www.cms.hhs.gov/MLNProducts/Downloads/Form_Exceptions_final.pdf.

Generics Boost Medicare D Savings

At least 14 brand name drugs are due to go off-patent in the next 5 years, representing $23 billion in potential savings to Medicare Part D, claims the Pharmaceutical Care Management Association in a new report. PCMA's members—managed drug benefit plans—negotiate discounts with drug makers on behalf of employers and insurers. The organization says that this year alone, $1.5 billion could be saved due to lost exclusivity on four drugs: Zoloft (sertraline), Zocor (simvastatin), Proscar (finasteride), and Pravachol (pravastatin). The savings assume that 90% of Medicare prescriptions would be switched to generics, and that the generic would cost 60% less than the brand. In 2007, Norvasc (amlodipine besylate), Ambien (zoldipem tartrate), Zyrtec (cetirizine), Lotrel (amlodipine/benazepril), Coreg (carvedilol), and Lamisil (terbinafine) are due to lose patent protection, which could lead to $700 million in savings that year.

Maryland Passes Stem Cell Bill

The Maryland legislature passed a bill establishing a $15 million fund to promote stem cell research in the state. The measure, which passed by a vote of 90-48 and was signed by Republican Gov. Robert Ehrlich, will establish procedures for reviewing research projects involving either adult or embryonic stem cells. An independent commission—including representatives from the patient advocate, biotechnology, and ethics communities—will administer grants to universities and private sector researchers.

FDA Names Drug Safety Spokesman

The Food and Drug Administration has appointed Dr. Paul Seligman as associate center director for safety policy and communication in the agency's Center for Drug Evaluation and Research (CDER). According to CDER director Dr. Steven Galson, "This step will help to provide a more standardized and predictable approach to ensuring drug safety and enhance the effectiveness and timeliness of the information we provide to the health care community and the public." But Dr. Sidney Wolfe, director of Public Citizen's Health Research Group, said in an interview that the appointment was just more window dressing. Dr. Seligman "will be reporting directly to Dr. Galson and will lack the independence necessary to free up the Office of Drug Safety from its second-class position in FDA." At a telephone conference, Dr. Seligman said that he still works for FDA, but "there are many important policy questions that go well beyond the FDA" when deciding whether to change labeling or pull a drug from the market. "Those issues will continue to be with us and will be decided on a drug-by-drug basis."

Report Critical of HRSA

The Health Resources and Services Administration needs to do a better job of making workforce projections, according to a report from the Government Accountability Office. "HRSA has in the past decade published national supply and demand projections for the nurse and pharmacist workforces but no national projections for the physician and dentist workforces," the GAO said in its report. In its response, HRSA stated, "we believe that the legislated goal of providing 'health workforce information and analysis, …such as shortages of registered nurses, shortages of pharmacists, and the distribution of health care workers in underserved areas,' is broader than what GAO's exclusive focus on supply and demand projections for physicians, nurses, and dentists would allow."

Welfare Reform? More Uninsured

The welfare reform act passed in 1996 has resulted in more rural citizens becoming uninsured, according to a report from the National Rural Health Association. The report also found that people were more likely to become uninsured if they got jobs after leaving welfare, compared with those who remained unemployed (28% vs. 20%).

—Joyce Frieden

Push for Generic Insulin, HGH Approval Guidelines

BY JOYCE FRIEDEN
Associate Editor, Practice Trends

The Food and Drug Administration plans to hold off on issuing approval guidelines for generic insulin and human growth hormones, despite pressure from congressional leaders.

Instead, the agency will offer broader guidance on follow-on proteins in general, Patrick Rowan, FDA associate commissioner for legislation, wrote to Sen. Orrin Hatch (R-Utah) and Rep. Henry Waxman (D-Calif.), in response to their letter.

"FDA expects that this approach will provide useful guidance to the industry, while ensuring that we do not stifle innovation and the utilization of state-of-the-art technologies," Mr. Rowan wrote. "FDA's consideration of regulatory requirements for these products has not stalled and …we are moving ahead as quickly as resources will allow." He pointed out that the agency already has approved several follow-on protein products that meet FDA criteria, including human recombinant hyaluronidase (Hylenex), calcitonin-salmon recombinant (Fortical Nasal Spray), and glucagon recombinant (GlucaGen).

In their letter, Sen. Hatch and Rep. Waxman noted that the agency has been working on guidance documents for generic insulin and human growth hormone for 4 years.

"In 2002, FDA officials drafted guidance documents providing the requirements for approval of generic forms of insulin and human growth hormone," they wrote. "Since that time, the agency has held public workshops and public meetings on various issues pertaining to generic biologics, but it apparently decided to defer the release of the guidance documents for insulin and HGH until it had resolved issues pertaining to the entire class of biologics.

"Now, several years later, the effort to develop the appropriate regulatory requirements for generic biologics appears to be at a complete standstill," the legislators wrote. "It is time for FDA to clarify what data it will require that manufacturers provide when seeking to market a generic insulin or HGH product."

Rather than waiting for guidance on the broader category to emerge, Sen. Hatch and Rep. Waxman argue that generic insulin and human growth hormone are simpler than other follow-on protein products and therefore should have guidance documents issued for them now.

"[Insulin and human growth hormone] have relatively simple structures with a long history of safe use by millions of people," they wrote. "Moreover, because both of these products currently are regulated under the federal Food, Drug, and Cosmetic Act, establishing the approval requirements for their generic forms does not raise the legal issues that exist with approval of generic forms of [other follow-on protein] products. The legal framework for such approval already exists."

Dr. Bill Law Jr., president of the American Academy of Clinical Endocrinologists, said that waiting for more general guidance would not be such a bad idea.

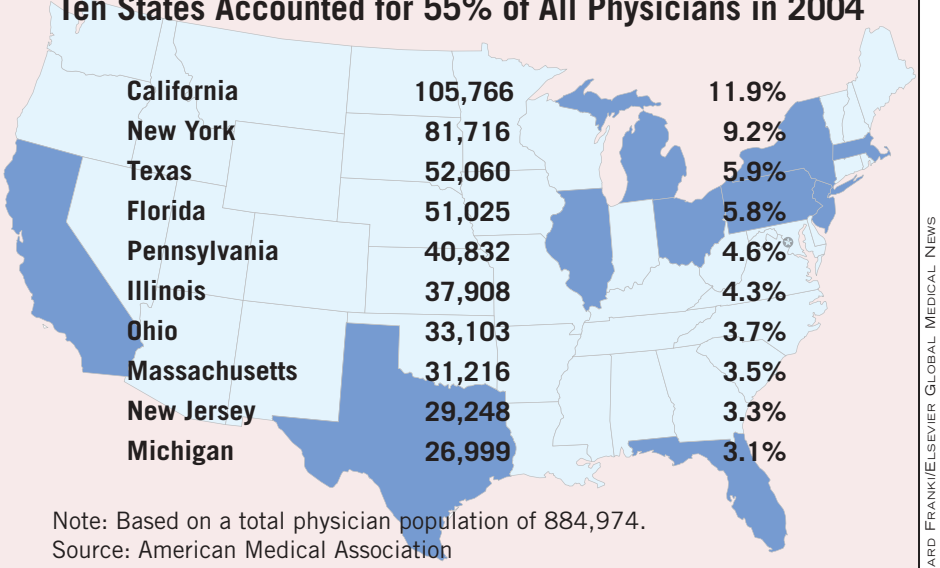
"Obviously, having less expensive biologicals would make it easier for patients to afford to actually purchase and administer them when prescribed, so it would be good for both patients and their physicians," Dr. Law said in an interview. "However, an inexpensive product that is either unsafe or ineffective is not a good bargain."

He noted that he talks daily with patients who are concerned about difficulty in paying for biologicals and medications.

"However, I'm sure that they would rather continue to pay for a branded product that has proved to be safe and effective in human clinical trials than to be included later as a subject in a scientific article documenting major safety and/or efficacy deficiency problems in a generic biological product that was approved for use in humans based on poorly thought-out requirements created urgently because of political pressure by well-intentioned but scientifically naive legislators," Dr. Law said. ■

DATA WATCH

Ten States Accounted for 55% of All Physicians in 2004



Note: Based on a total physician population of 884,974.
Source: American Medical Association

Richard Frank/Elsevier Global Medical News