POLICY & PRACTICE

Fla. Ruling Affects Levothyroxine Rx

A ruling by a Florida administrative law judge means pharmacists in that state now are free to substitute generic levothyroxine sodium for brand-name formulations of the drug. The January decision that removed Synthroid, Levoxyl, Levothroid, and Unithroid from the negative formulary list came in response to a petition last August by Mylan Inc., which markets a generic form of levothyroxine. Prescriptions for drugs on a negative formulary list may not be substituted. Judge Susan B. Harrell noted in her decision that Abbott argued that removing levothyroxine from the negative drug formulary would endanger patients because pharmacists could substitute a generic drug which is not therapeutically equivalent to the prescribed brand-name drug. However, that issue is already covered by existing laws on generic substitution, she added. "The legislature has left it to the professional judgment of licensed pharmacists to determine what substitutions would not pose a threat to the health and safety of the patients," Judge Harrell wrote. In an alert to its Florida members, the American Association of Clinical Endocrinologists noted that as a result of the ruling, "the only way to ensure your prescription or refill order is honored to your specifications is to write 'Medically Necessary' on the prescription." Abbott Laboratories, which makes Synthroid, has filed an appeal.

Baseball Drug Exemptions Skyrocket

The number of "therapeutic use exemptions" given to Major League Baseball players tripled between 2006 and 2007, according to statistics recently released by the House Oversight and Government Reform Committee. In 2007, MLB granted 111 exemptions, compared with 35 in 2006. Of the 111 exemptions granted last year, 103 were for medications to treat attention-deficit/hyperactivity disorder; 5 were for treating hypertension, 1 was for treating alopecia areata, and 2 were for treating androgen deficiency. Of the 35 granted in 2006, 28 were for ADHD, 4 were for hypertension, and 3 were for androgen deficiency. The ADHD exemptions in 2007 "would appear to be an exceptionally high percentage, somewhat over … eight times the percentage of regular adults taking [ADHD] medication in our population," John Tierney (D-Mass.), committee member, said at a hearing on steroid use in Major League Baseball. MLB Commissioner Bud Selig said the exemptions were "within the limit of the adult population. …We are reviewing that right now, trying to break down exactly why it happened and how it happened."

Pay for Remote Monitoring

Reimbursement for remote monitoring may be added to a Medicare physician fee fix bill when it is taken up later this year, officials from AdvaMed, a lobbying group for medical device companies, said at a briefing last month. AdvaMed has met with staff from the Centers for Medicare and Medicaid Services to discuss coding for remote management of conditions such as heart failure, cardiac arrhythmia, diabetes, sleep apnea, and epilepsy. The coding discussions may provide the necessary momentum, said Stephen J. Ubl, AdvaMed president and CEO. The device lobby estimates that remote monitoring would cost $100 million or less over a 5-year period. Mr. Ubl also expressed hope that the Medicare package will include funds for a demonstration project to test a new payment system for certain molecular diagnostics. That would fix a flawed system, which pays less for new tests that may offer greater value to patients, he said. The pilot proposal is in S. 2404, which is sponsored by Sen. Chuck Schumer (D-N.Y.).

ACC on Vytorin Queries

The American College of Cardiology said it is cooperating with the House Energy and Commerce Committee on its requests to furnish information on funds the college has received from Merck & Co./Schering-Plough Corp., the joint venture that makes and sells Vytorin (ezetimibe/simvastatin). The drug combination has been the subject of intense scrutiny by the committee, largely because of delays in releasing data from the ENHANCE study. The committee said it wanted to know the nature of financial contributions made by the drug companies because the ACC and the American Heart Association had issued statements urging patients not to stop taking Vytorin without talking to their physicians first. The committee also requested data from the American Heart Association. Rep. Bart Stupak (D-Mich.), chairman of the oversight and investigations subcommittee, said his panel would look at "how they use this funding and any potential conflicts of interest." An ACC spokesperson said the organization had delivered boxes of material to the committee, adding, "industry support in no way affects our policies."

—Joyce Frieden