

POLICY & PRACTICE

Bill Seeks Consent for Off-Label Rx

A new bill in the California assembly would require physicians and surgeons to get informed consent from their patients before “prescribing, administering, or furnishing” a prescription for off-label use. A failure to adhere to the requirement would be considered a violation of the Medical Practice Act, which means physicians could be charged with a crime. The California Medical Association opposes the legislation. In a statement, the CMA said existing law is enough because physicians can be held liable for not disclosing risks. Off-label use often saves lives, the statement said. A.B. 2856 was introduced by Assemblywoman Loni Hancock (D-Berkeley). It would require physicians to specify that a medication is not approved by the Food and Drug Administration for the use that the doctor is recommending, that the risks are unknown, and that there is not a consensus on the drug’s efficacy. A patient could withdraw consent at any time.

Women’s Heart Health

A group of female lawmakers has introduced a bill to require gender-specific data in new drug and device applications and to expand free screening for low-income women. The HEART (Heart Disease Education, Analysis and Research, and Treatment) for Women Act (S. 2278) was introduced by Sens. Debbie Stabenow (D-Mich.) and Lisa Murkowski (R-Alaska). Reps. Lois Capps (D-Calif.) and Barbara Cubin (R-Wyo.) introduced the House companion bill (H.R. 4747). Few people realize that heart disease is the No. 1 killer of women, said Rep. Capps in a statement. The bill seeks to fund an education awareness campaign for physicians and patients, and to bar Food and Drug Administration approval of a drug or device if it does not include gender, race, and ethnicity data. It also calls for an annual report on women and heart disease to be compiled by the Agency for Healthcare Research and Quality and for hospital-quality data to be reported by gender. Finally, the bill would expand the WISEWOMAN (Well-Integrated Screening and Evaluation for Women Across the Nation) heart disease and stroke screening program from 14 states to all 50. The bill is supported by the American Heart Association, the American Stroke Association, and the National Coalition for Women with Heart Disease.

Smoking Rates Drop

The number of cigarettes sold in the United States in 2005 dropped 4.2% from 2004, the largest 1-year percentage decrease in sales since 1999, according to figures compiled by the Treasury Department. “We are pleased to see that the long decline of cigarette consumption is continuing,” Cheryl Heaton, Dr.P.H., president of the American Legacy Foundation, said in statement. “We also know that for the first time in the United States, there are more former smokers than current smokers.” The National Association of Attorneys General also applauded the numbers, noting that the drop continues

“the unprecedented long-term decline in cigarette smoking that began with the settlement of lawsuits” brought by state attorneys general against the major tobacco companies.

Survey: Part D Enrollees Happy

A new survey of Medicare beneficiaries who are receiving Part D drug benefits finds them to be largely satisfied. The survey—conducted 10 weeks into the new coverage—was paid for by America’s Health Insurance Plans, and conducted by Ayres, McHenry & Associates Inc., a Republican polling firm. The poll surveyed 408 of the 5.2 million people over age 65 years who have self-enrolled in Part D, and 401 of the 6.5 million “dual eligibles,” who were automatically enrolled because they had Medicaid drug coverage. Of those who self-enrolled, 66% said that it had been worth the time and effort to enroll, and four-fifths (84%) said that they had no problem signing up. The majority—85%-90% of both groups—said they had no problem using the new benefit. Ron Pollack, executive director of the advocacy group Families USA, said it was not surprising that beneficiaries who went to the trouble to sign up were happy. Shockingly few have signed up, however, said Mr. Pollack. According to the poll, among those who regularly take a prescription drug—90% of the self-enrolled and 83% of dual eligibles—79% said the plan covered the drugs they needed. Mr. Pollack said that was a step backward for the low-income group, who had 100% coverage under Medicaid. A little more than half (59%) of self-enrolled seniors said they are saving money. Forty-six percent of the self-enrolled and 35% of automatically enrolled seniors said Part D critics were bashing the plan to score political points; 14% in both groups said politicians were sincerely trying to fix the plan; about half were undecided.

Patient/Doctor Decision Making

Decisions about medical treatment should be made by physicians and patients, according to a survey of 1,029 adults for the National Consumers League. More than 90% of respondents agreed that, “[all] medications, both over-the-counter and prescription, offer benefits but also carry some risk of side effects. It should be up to physicians and patients to weigh benefits against the risks and to make decisions that are right for them,” according to the survey. The poll also found that the public strongly supports broader access to treatments—even those carrying additional risks—for chronic diseases such as multiple sclerosis, Parkinson’s disease, and Alzheimer’s disease. “Everything in life carries risks, but in the case of chronic, debilitating conditions, the greatest risk is a lack of new and improved treatment options,” said Linda Golodner, the league’s president. “It obviously makes sense for these patients to have access to as many treatment options as possible and make decisions that are right for them, even if there are additional risks.”

—Alicia Ault

Senators Battle Over Part D Rx Problems

BY JOYCE FRIEDEN

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WASHINGTON — Does your Medicare patient need a prescription for a drug not on his or her drug plan formulary? Be forewarned: You may have to fill out pages of forms.

“There continue to be widespread reports of drug plans requiring prior authorization for beneficiaries to receive needed medication,” Sen. Hillary Rodham Clinton (D-N.Y.) said during a hearing of the U.S. Senate Special Committee on Aging. “Some reports have plans requiring forms for each drug, while others are requiring doctors to fill out forms as long as 14 pages for drugs that a beneficiary has been taking for years.”

Addressing her remarks to Dr. Mark B. McClellan, administrator of the Centers for Medicare and Medicaid Services and the hearing’s first witness, Sen. Clinton continued, “Your agency’s request that plans discontinue this practice does not seem to be working. ... I hope that you will require, not request, that the plans cease this practice and enforce that requirement.”

In his prepared testimony, Dr. McClellan noted that CMS has “developed specific procedures for timely exceptions and appeals. Using those procedures, a Medicare beneficiary can get coverage for a drug that is not on a plan’s established formulary.”

He also acknowledged, however, that the plan rollout was not without problems. “We make no excuses for these problems,” he said “They are important, they are ours to solve, and we are finding and fixing them.”

Many of the problems with getting prescriptions filled occurred in the dual-eligible population—patients who qualified for both Medicare and Medicaid. “These often are the poorest and most vulnerable Americans who rely on medications to manage their chronic physical and mental illnesses,” noted

committee chairman Gordon Smith (R-Ore.) “We knew there would be challenges associated with their transition from Medicaid into the new Medicare drug benefit, but it seems that perhaps not enough was done to ensure a seamless transition.”

As a result of the problems with the drug benefit, “pharmacists are not getting paid on time and have to take out loans to pay their bills and keep their doors open,” said committee member Blanche Lincoln (D-Ark.). “These problems could have been avoided.”

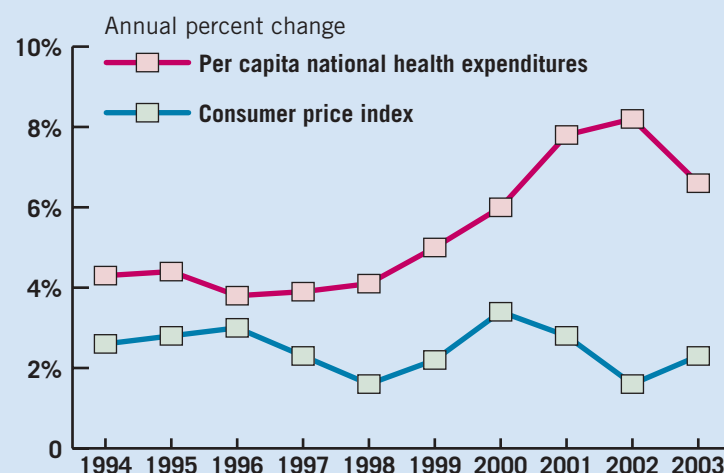
Sen. Clinton said the problems were so bad that she was ready to give up. “I for one believe we should scrap this and start over. We are spending hundreds of billions of dollars on an inefficient delivery of a plan that could be done in a much more cost-effective way,” she said.

But Sen. Rick Santorum (R-Pa.) disagreed. “Throwing it out would doom seniors to a situation where they would be getting less care than they are today.”

Committee member Conrad Burns (R-Mont.) also weighed in. “We Americans are in this business that everything has to be instant—tea, coffee, everything that we do, and we’re supposed to have a new program put in place and all at once it’s perfect,” he said. “I would ask my colleagues [to just] get the program in place; that serves our purpose, and then we know what to fix. Right now, we don’t know what to fix.”

One thing Sen. Smith said that he wants to fix is the part of the program that requires dual-eligible patients living at home or in an assisted living facility to pay copayments for drugs received under the program; currently, only dual-eligible patients in nursing homes are exempt from copayments. Sen. Smith introduced a bill eliminating the copayments for dual-eligible patients in home- or community-based care; the measure, which was cosponsored by Sen. Jeff Bingaman (D-N.M.) was still being considered at press time. ■

DATA WATCH

Rise in National Health Expenditures Slows

Source: The Henry J. Kaiser Family Foundation