

California Plan Would Ban Step-Therapy Insurance Mandates for Pain Medications

SACRAMENTO, Calif.—California could become the second state in the nation to ban the health insurance industry practice of requiring patients to try less-expensive, often over-the-counter medications, before covering pain treatments recommended by doctors.

Under protocols known as “step-therapy” or “fail-first” policies, outpatients must try alternative medications before insurance companies will pay for the course of pain treatment initially prescribed by a doctor.

A bill set for early August action in a key committee, A.B. 1826, would ban the practice, which industry credits for keeping costs down but patients' groups decry as inhumane.

The bill would affect health care service plan contracts regulated by the California Department of Managed Health Care (DMHC) and health policies overseen by the California Department of Insurance (DOI), unless the state's public employee pension fund purchased the coverage.

If enacted, the law would affect approximately 18.7 million Californians who have health insurance subject to the bill, the California Health Benefits Review Program estimated in an April 2010 report to the Legislature.

Set for Aug. 2 Action

Introduced by Assemblymen Jared Huffman (D-San Rafael) and Mike Feuer (D-Los Angeles), the bill was approved June 2 on a 45-26 vote by the Assembly and now is pending in the Senate, amid strong industry opposition.

The Senate Appropriations Committee has the closely watched bill on its Aug. 2 agenda.

As of July 20, the bill would ban insurers that cover prescription drugs from excluding a medication from coverage if prescribed outside its U.S. Food and Drug Administration approved use, as long as the medication is to treat a chronic and seriously debilitating condition and the drug is on the plan formulary.

Health insurers' representatives in Sacramento say step-therapy reduces costs and the risks of patient dependence on prescription painkillers. Banning the

practice, they say, will increase health insurance premiums and drug costs.

“This bill represents a significant expansion of coverage and it will result in unintended consequences because it mandates payment for any drug prescribed for pain while weakening policies designed to minimize harmful side effects,” Nicholas Louizos, director of legislative affairs for the California Association of Health Plans (CAHP), wrote in a June 23 letter to Senate lawmakers urging them to reject the Assembly-approved bill.

For its part, Blue Shield of California said in an opposition letter step-therapy protocols also “act as a check-and-balance to the cozy relationship that exists between many physicians and drug companies.”

The bill exempts health plans purchased through the California Public Employees' Retirement System (CalPERS), the nation's largest public employee pension fund.

“The best evidence of the high cost of this bill is that it completely exempts the CalPERS system,” the CAHP opposition letter said. “While this spares the public employers from the cost of this bill, it means that private employers will be expected to shoulder the cost instead.”

A 2008 PriceWaterhouseCoopers study, *The Factors Fueling Rising Healthcare Costs 2008*, found prescription drugs consume about 14 cents of every health premium dollar, and while brand-name pain prescriptions account for just 12 percent of all pain medication prescriptions, they account for more than 54 percent of the costs for this class of drugs, CAHP said in a fact sheet.

Unions, Patient Groups Support Bill

Supporters of A.B. 1826 include the American Pain Foundation, Alliance for Patient Access, American GI Forum of California, Association of California Neurologists, Healthy African American Families, and the Urban Health Institute.

The lead sponsor of A.B. 1826 is For Grace, a Los Angeles-based advocacy organization for women with chronic pain formed by Cynthia Toussaint, a former ballerina who has suffered with complex regional pain syndrome (CRPS) for nearly 28 years, following a hamstring injury.

Toussaint told BNA step-therapy policies “get between that sacred patient-doctor relationship” by allowing “a bureaucrat who only cares about money” to make decisions about how patients' pain is treated.

Prospects for Legislation

Toussaint said she fully expects the bill to pass the Legislature, but worries Gov. Arnold Schwarzenegger (R) might veto the bill, since the bill received no Republican support in the Assembly.

“I think Governor Schwarzenegger wants the best for everyone, and this is the right thing to do,” she said. “I hope he signs it. If he vetoes it, I have my plan. I want to set up a [state] pain management commission,” such as one that is operating in Oregon.

Schwarzenegger spokeswoman Rachel Arrezola told BNA the governor has not taken a position on the bill.

A.B. 1826's provisions would be outlined in Section 1367 of the California Health and Safety Code and in Section 10123 of the California Insurance Code.

The legislation would require health plans with prescription drug benefits and formularies to provide, upon request, a copy of the most current list of prescription drugs by therapeutic category, with an indication of whether any drugs on the list are preferred over other listed drugs.

Plans also would be required to have an “expedited process” by which physicians could get authorization to prescribe a nonformulary drug. The bill would not have jurisdiction over doctors' prescribing habits, only over pharmacy benefits paid by insurers.

Bill Would Increase Expenditures

The California Health Benefits Review Program (CHBRP) estimates the bill would raise costs to the state's Medicaid program, Medi-Cal, by about \$8.1 million, or 0.2 percent. State expenditures for Healthy Families, the Aid to Infants and Mothers (AIM) program, and the Major Risk Medical Insurance Program (MRMIP) are estimated to increase by about \$2.10 million, or 0.23 percent.

The differences would mark an increase of 24 cents per member per month (PMPM) for Medi-Cal, Healthy Families, AIM, and MRMIP.

As for other market segments, legislative analysts estimated PMPM increases of 8 cents in large-group market DMHC-regulated plans, 11 cents in large-group DOI-regulated policies, 11 cents in small-group market DMHC-regulated plans, 17 cents in small-group market DOI-regulated policies, 10 cents in individual market DMHC-regulated plans, and, 10 cents PMPM in individual market DOI-regulated policies.

There are about 18.7 million enrollees in state-regulated health plans who could be affected by the bill, the California Health Benefits Review Program report indicated.

CHBRP said 18.1 million, or 97.2 percent, of insured Californians have outpatient pharmacy benefits coverage. Of these, 8.3 million enrollees, or 45.5 percent, have pharmacy coverage subject to fail-first protocols for one or more

pain medications. Meanwhile, about 9 million enrollees, or 49.3 percent have pharmacy coverage that is not subject to any fail-first protocols.

Also not affected would be 417,000 enrollees who have generic-only outpatient pharmacy benefits coverage and 521,000 insured Californians who forgo outpatient pharmacy coverage, CHBRP estimates.

CHBRP is administered by the Office of Health Sciences and Services at the University of California's Office of the President in Oakland, Calif.

New Jersey Went First

New Jersey is the only state that currently bans step therapy in pain treatment. Missouri has legislation pending.

Last year, the federal Centers for Medicare & Medicaid Services (CMS) limited step therapy for Medicare patients, to two failures before providing access to the prescribed medicine. Medicare Part D drug plan sponsors must post online quantity limit restrictions and step therapy requirements, under the 2010 call letter from March 2009.

Federal regulations bar health insurers from requiring Medicare patients to try an off-label drug before providing a medication approved by the Food and Drug Administration for the condition, the call letter said.

“For contract year 2010, drugs identified on a Part D sponsor's formulary flat file with prior authorization (PA) or step therapy must have corresponding utilization management (UM) criteria,” reflected in their Health Plan Management System, the CMS letter said.

Study Examines Cost Effects of Step Therapy

An industry-sponsored study published in the February 2009 American Journal of Managed Care examined the cost effects of step therapy on employers.

After examining insurance claims, from 2003 to 2006, of 11,851 patients with employer-sponsored health coverage who used antihypertensive agents, researchers said they found a 3.1 percent reduction in medication costs in policies requiring step therapy, compared to data from a group of 30,882 antihypertensive drug users who did not participate in a step therapy program.

Researchers conducting the Pfizer Inc.-sponsored study said the savings found in step-therapy plans were eliminated once hospital admissions and emergency room visits were included.

“The intended effect of step therapy is to substitute less expensive and equally or more effective medications for more expensive medications,” the researchers

concluded. “As this study demonstrates, step therapy may create barriers to receiving medication, resulting in higher medical healthcare utilization and spending. Clearly, there is a need for additional research to understand both the strengths and limitations of step therapy.”

By Chris Rizo

The California Health Benefits Review Program report is available at http://www.chbrp.org/docs/index.php?action=read&bill_id=70&doc_type=2.

The 2009 journal study on step therapy is at <http://www.ajmc.com/issue/managed-care/2009/2009-02-vol15-n2/Feb09-3917p123-131>.