Plan to Limit Some Drugs in Medicare Is Criticized

New York Times

By KATIE THOMAS and ROBERT PEAR FEB. 22, 2014

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An alliance of drug companies and patient advocates, joined by Democrats and Republicans in Congress, is fiercely opposing an Obama administration proposal that would allow insurers to limit Medicare coverage for certain classes of drugs, including those used to treat depression and schizophrenia.

Opponents warn that the proposal, if enacted, could harm patients. Federal officials say it would lower costs and reduce overuse of the drugs.

The proposed rule, which would lift a requirement that insurers cover "all or substantially all" drugs in certain treatment areas, is just one of a series of changes to the drug program that are being opposed by the unlikely alliance. Even insurers and drug benefit managers, who have previously supported added limits on drug coverage, oppose the rule. They object to provisions including changes to so-called preferred pharmacy networks, where consumers are steered toward a limited network of pharmacies, and to reducing the number of plans that insurers can offer in any one region.

A House subcommittee plans to hold a hearing on the proposal next week, and the rule is open for public comment until March 7.

"We've been scratching our heads over this," said John J. Castellani, the chief executive of the Pharmaceutical Research and Manufacturers of America, the drug-industry trade group. Medicare Part D, he noted, is the rare government program that not only gets high marks from consumers but also has cost taxpayers billions of dollars less than originally expected. "Why is the administration trying to make such extensive changes to a program that isn't broken?"

Mr. Castellani's organization was one of more than 200 groups that signed a letter this week asking that the rule be withdrawn. Earlier this month, Republican and Democratic members of the Senate Finance Committee warned that the proposal could "diminish access to needed medication" without saving much money.

The administration's proposal would remove the protected status from three classes of drugs that has been in place since the program's inception in 2006: immunosuppressant drugs used in transplant patients, antidepressants and antipsychotic medicines. They include many well-known drugs, such as Wellbutrin,Paxil and Prozac to treat depression, and Abilify and Seroquel to treat schizophrenia. Three other categories — cancer, H.I.V. and anti-

seizure drugs — would retain their status as protected classes and insurance companies would be required to continue covering nearly all drugs in those treatment areas. Medicare has traditionally required the broad coverage because patients with these conditions must often try several drugs before finding one that works.

In proposing the change last month, the administration said that the policy was envisioned as a temporary measure to help ease patients' transition to the new Medicare drug program, and that since then, insurers had lost their leverage in negotiating with drug companies because the drug companies knew the insurers were required to cover their drug costs and were therefore less willing to offer lower prices.

In its proposal, the Obama administration cited a 2008 study by the actuarial and consulting firm Milliman that showed that the six protected classes accounted for anywhere from 17 to 33 percent of total outpatient drug spending under Part D of Medicare. In addition, it said that the costs of those drugs were on average 10 percent higher than they would be without the requirement to cover substantially all drugs in these classes.

The administration predicted savings for both beneficiaries and the Medicare program if prescription drug plans could remove some currently covered drugs from their formularies. It could also give insurers additional tools to limit overuse of certain drugs, such as the prescribing of antipsychotic drugs to nursing-home patients with dementia, a common practice that is widely viewed as inappropriate.

"We believe the Part D program has been a phenomenal success," said Jonathan Blum, principal deputy administrator of the Center for Medicare and Medicaid Services, which oversees the Part D program. But, he added, "We also see vulnerabilities in the program, and we have proposed for public input into ways to improve it."

Leaders of numerous patient advocacy groups, many of whom met last week with White House officials to express concern about the proposed rule, said they were worried that patients could be harmed if the policy changed.

"The proposal undermines a key protection for some of the sickest, most vulnerable Medicare beneficiaries," said Andrew Sperling, a lobbyist at the National Alliance on Mental Illness.

Under the proposal, Mr. Sperling said, a Medicare drug plan could have a list of preferred drugs with just two medications to treat schizophrenia. That is inadequate, he said, because antipsychotic drugs work in different ways in the body, and have different side effects. "You get much better outcomes when a doctor can work with patients to figure out which medications will work best for them," he said.

In a letter written by members of the Senate Finance Committee, the senators suggested that the change could raise costs in other areas. "If beneficiaries do not have access to needed medication," the letter said, "costs will be incurred as a result of unnecessary and avoidable hospitalizations, physician visits and other medical interventions."

The new federal health care law requires that Medicare drug plans include all drugs in certain categories and classes "of clinical concern," and it authorized the secretary of health and human services to identify those categories.

Mr. Sperling said lawmakers had assumed that Medicare officials would keep the original six protected classes and add to them, not cut them. The administration proposal sets a high standard for designating protected classes, saying the drugs must be needed to prevent "hospitalization, persistent or significant disability or incapacity, or death" that would otherwise occur within a week.

Emily Shetty, a lobbyist for the Leukemia and Lymphoma Society, said Medicare beneficiaries, who include older and disabled Americans, should be treated with special care. "They are a more vulnerable patient population as a whole, and having access to a full range of therapies is crucial to ensure that they are able to get the care that they need," she said.

The Medicare Part D program is unusual in that it requires broad coverage of drugs in these categories. Commercial insurance plans, including those in the new marketplaces operating under the federal health care law, have more flexibility. Some drugs are simply not covered, and some plans require that patients and doctors go through additional steps — such as trying other drugs first, or getting approval from the insurer — before a drug will be paid for.

Insurers and the companies that manage their drug benefits argue that this arrangement has worked well for consumers, ensuring that drugs are being used properly and helping to keep prices low. But others have identified what they describe as a worrying trend toward more limited drug coverage, and higher out-of-pocket costs for the most expensive drugs.

The rule has some supporters, and many groups back some aspects of the proposal while opposing others.

"Just because a program is popular doesn't mean that it's being run the most efficiently, and at the best value for taxpayers and patients," said B. Douglas Hoey, chief executive of the National Community Pharmacists Association, which supports many aspects of the rule.

A version of this article appears in print on February 22, 2014, on page B1 of the New York edition with the headline: Plan to Limit Some Drugs in Medicare Is Criticized.