

Medicare Rules Set Off a Battle on Drug Choices

By ROBERT PEAR

ASHINGTON, Sept. 25 - The new Medicare law has touched off a huge battle between insurance companies and drug companies that could determine how many medicines will be readily available to Medicare beneficiaries.

Under the law, Medicare will rely on private health plans to deliver drug benefits to the elderly and disabled. The government will not specify precisely which drugs must be covered. Rather, each plan will develop a list of drugs approved for reimbursement.

In general, drug companies want as many drugs as possible on each list, known as a formulary. Many doctors and consumer groups agree. But insurers and drug benefit managers generally want to limit the number of drugs, and the types of drugs. Otherwise, they say, the new drug benefit will quickly become unaffordable.

"We are in a tug of war with the drug companies," said Phillip J. Blando, vice president of the Pharmaceutical Care Management Association, whose members manage drug benefits for 200 million people.

Pharmaceutical companies stand to gain or lose billions of dollars depending on whether their drugs or competing products are included in Medicare formularies.

The Bush administration has retained a private nonprofit organization, the United States Pharmacopeia, to develop a list of the types of drugs that should be covered. The guidelines, which serve as a model for private plans providing the new drug benefit, list 146 distinct categories and classes of drugs.

A broad therapeutic category, like antihistamines or heart medications, typically includes several classes. Under the law and rules announced by the Bush administration, private plans must cover at least two drugs in each category and class.

The formularies could have a major impact on the success of the new law, determining how many people sign up for drug benefits and how many private plans participate. Before enrolling in a plan, beneficiaries will presumably check to see if it covers the drugs they are taking.

A health plan generally does not have to pay for drugs excluded from its formulary, and while beneficiaries can use their own money to buy such drugs, the costs will not count toward the annual limit on their out-of-pocket expenses. After reaching that limit (\$3,600 a year in 2006), the beneficiary is entitled to catastrophic coverage, meaning that Medicare pays about 95 percent of drug costs beyond that amount.

The debate over formularies has produced some odd allies and adversaries. Drug companies have joined patients in arguing that patients should have access to the full

array of drugs for AIDS, asthma, depression, diabetes, epilepsy, multiple sclerosis, osteoporosis and other diseases.

Some Democrats, including [Senator John Kerry](#), the party's presidential nominee, have denounced the law as a giveaway to insurance and pharmaceutical companies. But those two industries now find themselves fundamentally at odds over how to carry out the law they lobbied hard to enact.

Howard J. Bedlin, vice president of the National Council on the Aging, a research and advocacy group, said, "A restrictive formulary with a limited number of therapeutic classes may save money in the short run, but it will cost Medicare and beneficiaries more in the long run," by increasing the need for hospital care, nursing home admissions and doctors' visits.

"If beneficiaries discover that the drugs they take are not covered under the plans available in their area, many may choose not to enroll," Mr. Bedlin said, and that could drive up premiums for those who do enroll.

Richard I. Smith, senior vice president of the Pharmaceutical Research and Manufacturers of America, a lobby for brand-name drug makers, said the list of drug classes must be expanded to ensure that Medicare beneficiaries have access to the drugs they need and use.

"A formulary could comply with the U.S. Pharmacopeia's guidelines while excluding coverage for 41 of the 50 drugs most commonly used by seniors," Mr. Smith said. The 41 drugs, he said, include Lipitor and Zocor for high cholesterol, Norvasc for high blood pressure, Fosamax for osteoporosis, Celebrex and Vioxx for arthritis, Nexium for heartburn, Zoloft and Paxil for depression and Allegra for allergies.

Joseph W. Cranston, science director of the American Medical Association, said doctors were "deeply concerned" that the formulary guidelines could deny Medicare patients access to some valuable drugs.

Until now, Medicare had no outpatient drug benefit. In Congressional debate last year, lawmakers said it was absurd that Medicare would pay \$8,000 to hospitalize a person for a heart attack, but not \$80 a month to provide drugs like Lipitor that could help prevent heart attacks by reducing cholesterol. But Dr. Cranston, a pharmacologist, said the guidelines did not require prescription drug plans to cover the type of drugs most widely used to treat high cholesterol, known as statins.

Dr. Hans Vemer, senior vice president of the Schering-Plough drug company, said that by limiting coverage of such products, prescription drug plans could "avoid attracting large numbers of patients with serious heart disease" and other chronic illnesses.

The law forbids discrimination against people with high drug costs, but insurers may have powerful incentives to discourage the enrollment of such patients. On average, Mr.

Smith said, the drug costs for a Medicare recipient with heart disease or diabetes are twice as high as the drug costs for all other beneficiaries.

Senator Charles E. Grassley, Republican of Iowa, said Medicare officials could require insurers to modify their formularies if they were found to discriminate against people with mental illness, AIDS or other conditions. Congress wanted beneficiaries to have access to "a wide range of prescription drugs," and in some cases, that will require more than two drugs of a particular type, said Mr. Grassley, a principal author of the new law.

Andrew Sperling, a lobbyist at the National Alliance for the Mentally Ill, said the guidelines made "a serious mistake" by lumping a vast array of treatments for depression in a single class. As a result, he said, a drug plan could include two older drugs on its formulary while excluding newer, more effective antidepressants that cost more.

"These drugs are not interchangeable," Mr. Sperling said.

But managed care companies and benefit managers oppose any increase in the types of drugs that must be covered. They complain that drug makers are continually pushing for coverage of their latest, most expensive products, even when older drugs are just as effective for most patients.

"The drug makers' agenda could seriously undermine Medicare's ability to maintain an affordable benefit," said Mark Merritt, president of the Pharmaceutical Care Management Association, which represents companies like Medco and Express Scripts.

Blue Cross and Blue Shield plans say the 146 classes and categories of drugs could be compressed. "Requiring coverage of drugs in too many categories will diminish the ability of drug plans to negotiate favorable prices," said Alissa Fox, policy director for the Blue Cross and Blue Shield Association.

Health plans and pharmacy benefit managers say they typically receive discounts from the manufacturer of a drug if sales reach a certain level - say 40 percent of all the prescriptions for cholesterol-lowering agents.

Judith A. Cahill, executive director of the Academy of Managed Care Pharmacy, which represents pharmacists who work for health plans, said, "An excessive number of therapeutic classes reduces the drug plans' leverage" in negotiations with drug makers.

Medicare officials said they would evaluate all formularies to make sure they did not discourage the enrollment of sick people with high drug costs. The law says that the classification of drugs on a formulary will be presumed acceptable if it follows the guidelines of the United States Pharmacopeia.

Dr. Mark B. McClellan, administrator of the federal Centers for Medicare and Medicaid Services, said the government would also analyze other factors, like the co-payments

charged for various drugs, prior-approval requirements and appeal procedures for patients denied coverage of a drug.

"Our goal," Dr. McClellan said, "is to ensure that people can get the drugs they need at the lowest possible cost. The choice of drugs should reflect current medical practice."