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## New Medicare Rules on Drugs Balance Access Against Costs

By **ROBERT PEAR**

**W**ASHINGTON, Jan. 21 - The Bush administration on Friday unveiled rules for the new Medicare drug benefit that guarantee patients access to a wide variety of medicines while giving insurance companies potent tools to control costs.

Issuance of the rules is one of the most significant events between Dec. 8, 2003, when President Bush signed the Medicare law, and Jan. 1 next year, when the drug benefit becomes available.

The rules, which were made final after a long, contentious public comment period, will govern all who might be involved in the new program: health insurers, employers, drug manufacturers, pharmacies, benefit managers and up to 41 million elderly and disabled people covered by Medicare.

On many issues, the rules strike a balance between competing interests.

On the one hand, the rules say that every prescription drug plan must provide "adequate coverage of the types of drugs most commonly needed" by Medicare beneficiaries. These include drugs to treat high blood pressure, heart disease, cancer, osteoporosis and Alzheimer's disease.

On the other hand, the rules say that a plan can establish a list of preferred drugs and can refuse to pay for other medicines.

In general, the list, known as a formulary, must have at least two drugs for treating each condition or illness.

The rules do not dictate which specific drugs must be covered - for example, by specifying Paxil or Zoloft among the antidepressants, or Lipitor or Crestor among the cholesterol drugs. But Medicare officials said they could require insurers to cover "specific drugs" or types of drugs, to be identified in the future.

The rules also embody other important policy decisions that will determine exactly how the new program works and whether it succeeds. Consumers, insurers, drug companies and politicians have been

sparring over almost every detail of the rules.

The final rules address many concerns that people expressed about a preliminary version, issued in late July. One concern centered on the fact that Medicare will replace Medicaid as the source of drug coverage for many of the elderly poor.

About 6.3 million low-income people are enrolled in both insurance programs. Medicaid, which is financed jointly by the federal government and the states, now pays for their drugs, but will not do so after Jan. 1, 2006. State officials and advocates for low-income people had expressed alarm that many of these beneficiaries would lose coverage for months, while they moved from Medicaid to a Medicare drug plan.

Dr. Mark B. McClellan, administrator of the federal Centers for Medicare and Medicaid Services, said Friday that people eligible for the two programs would "have no gap in coverage" because they would be automatically enrolled in Medicare drug plans this fall.

The law, the biggest expansion of Medicare since its creation in 1965, depends on private health plans to deliver the new benefit. Insurers, eager to control costs, wanted to limit the number of drugs they must cover. Doctors, drug companies and advocates for beneficiaries wanted to maximize the number.

The government offered a compromise. It allows the use of formularies and says insurers must cover only one drug in a therapeutic category or class if only two drugs are available and one is clearly superior.

But if a doctor certifies that a particular drug is medically necessary for a patient, the drug plan must cover it, regardless of whether it is on the list of preferred medicines. Under the rules, the insurer "must grant an exception whenever it determines that the drug is medically necessary," and the insurer is supposed to accept the judgment of the prescribing physician on the question of medical necessity.

Dr. McClellan said the rules offered "comprehensive assistance for low-income beneficiaries," nearly 11 million of the 41 million elderly and disabled people on Medicare.

Many employers have cut retiree health benefits in the last 15 years. The law offers subsidies to employers to encourage them to continue providing drug benefits to retirees.

Dr. McClellan predicted that 9.8 million retirees would receive drug coverage from employer-sponsored health plans that qualify for the federal subsidies. This number, he said, is more than one million above the highest previous estimates.

The rules explain how a beneficiary can appeal the denial of coverage for a particular drug, and they set standards to ensure convenient access to drugstores.

Patients denied coverage can appeal through a complex, five-stage process. They can ask for a redetermination by their drug plan, a reconsideration by an outside organization, a hearing before an administrative law judge and a review by the Medicare Appeals Council, a unit of the Department of Health and Human Services. A beneficiary who is still dissatisfied can file suit in a federal district court.

Each prescription drug plan can establish a network of pharmacies that agree to sell drugs to Medicare patients at discounted prices. An insurer must have a large enough network so that 90 percent of the Medicare beneficiaries in urban areas live within two miles of a participating drugstore, and 90 percent of those in suburban areas are within five miles of a store.

Beneficiaries who sign up with a drug plan are generally locked in for a year. Insurers can end coverage for a particular drug, or increase the co-payment, if they give 60 days' notice to patients and the government.

The United States Chamber of Commerce, the Blue Cross and Blue Shield Association and America's Health Insurance Plans, a trade group for insurers, praised the new rules. Howard G. Phanstiel, chairman of PacifiCare Health Systems, a large insurer based in Cypress, Calif., said the rules showed that the government would be "a good business partner."

But consumer advocates, like Families USA and the Medicare Rights Center, said they were somewhat disappointed.

Judith A. Stein, director of the Center for Medicare Advocacy, a nonprofit group that counsels beneficiaries, said the rules allowed immense complexity and variation in benefits. Drug discount cards, offered as a temporary source of assistance, were too complex for many elderly people, she said, and the new drug benefit may be even more confusing.

Many states, like New York, New Jersey and Pennsylvania, have programs that assist state residents with their drug costs. The new rules say states cannot select one Medicare drug plan and enroll all their beneficiaries in that plan. Instead, states must work with all available drug plans.

Senator Jon Corzine, Democrat of New Jersey, said this requirement would disrupt a state program that had worked well for three decades.