



DEPARTMENT OF HEALTH & HUMAN SERVICES
Health Care Financing Administration

Center for Medicaid and State Operations
7500 Security Boulevard
Baltimore, MD 21244-1850

November 30, 1998

Dear State Medicaid Director:

The purpose of this letter is to advise States about the appropriate coverage of Viagra through the Medicaid program and to encourage States to ensure that appropriate medications are provided to the Medicaid population.

The issue of whether State Medicaid programs must cover Viagra is governed by the Omnibus Budget Reconciliation Act of 1990, which established the drug rebate program at section 1927 of the Social Security Act (the Act). This law requires, with a few limited statutory exceptions, that a State that chooses to include outpatient drugs within its Medicaid program must cover, for their medically accepted indications, all FDA approved prescription drugs of manufacturers that have entered into drug rebate agreements. The specific exceptions are contained in section 1927(d)(2) of the Act, which provides that a State may choose to exclude or restrict drugs or classes of drugs, or their medical uses for certain purposes. These exceptions include drugs when used: for anorexia, weight loss or weight gain; to promote fertility; for cosmetic purposes or hair growth; for the symptomatic relief of cough and colds; or to promote smoking cessation. States may also exclude prescription vitamins and mineral products (except prenatal vitamins and fluoride preparations); nonprescription drugs; drugs with respect to which the manufacturer seeks to condition the sale of the drug on a requirement that associated tests or monitoring devices be purchased exclusively from the manufacturer or its designee; barbiturates; and benzodiazepines.

The FDA has approved Viagra only to treat erectile dysfunction in men. Viagra does not fall within any of the allowable exclusions or restrictions listed in section 1927(d)(2), and section 1927(d)(3) of the Act provides for the Secretary to add a drug to that list only when she determines, based on data she has received from the States, that a drug is subject to clinical abuse or inappropriate use. Therefore, the law requires that a State's Medicaid program cover Viagra when medical necessity dictates such coverage for the drug's medically accepted indication.

Secretary Shalala is greatly concerned about the potential for clinical or financial abuse of Viagra. Therefore, HCFA intends to monitor this vigorously, working with States in their review of claims and other data to monitor utilization of Viagra. We will work with States, clinicians, consumer advocates and others to assure consistent collection of the data that would be necessary to make the determination contemplated by section 1927(d)(3).

In addition, States have several methods under the Medicaid program to ensure that they pay for Viagra and other drugs only when the proper diagnosis has been made and the drug is medically necessary. I understand some States are already taking some of these steps. I strongly urge you to consider some or all of the following measures to prevent abuse and misuse of Viagra and to ensure appropriate use and cost efficiencies:

- Implement procedures to ensure that physicians have undertaken the full medical assessments necessary to reach the correct diagnosis, to properly document this diagnosis, and to determine that Viagra is prescribed only when it is medically necessary;
- Take all measures necessary to assure Viagra is prescribed only for those for whom the drug is indicated and used only by those for whom it is prescribed;
- Monitor and discipline, as appropriate, providers who prescribe Viagra for medically inappropriate indications or when not medically necessary;
- Establish prior authorization programs to assure that health professionals meet their responsibilities in prescribing Viagra; and
- Place limits on the number of refills or the quantity per prescription to discourage waste, fraud, and abuse.

We will work with representatives of States to make communications on best practices available, so that successful techniques are shared among States. The challenge to both the States and the Federal government is to provide appropriate access to new drugs for the Medicaid population while performing the necessary oversight to assure that these drugs are being used in the appropriate medical circumstances for the appropriate segment of the Medicaid population. The fundamental agreement of the rebate legislation is responsible for ensuring Medicaid coverage of breakthrough pharmaceutical treatments such as protease inhibitors and atypical antipsychotic drugs. In partnership with the States, I feel assured that this challenge can be met.

Sincerely,

/s/

Sally K. Richardson,
Director

cc: All HCFA Regional Administrators; All HCFA Associate Regional Administrators for Medicaid & State Operations; Lee Partridge American Public Human Services Association; Joy Wilson National Conference of State Legislatures; Nolan Jones National Governors' Association