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In 1997, the Medicaid program paid nearly \$12 billion for prescription drugs. Next to physician services, it is the most frequently used benefit in the Medicaid program. [\(1\)](#) For beneficiaries with AIDS, mental illness or other chronic or disabling illnesses, the Medicaid prescription drug benefit is a virtual lifeline. But the benefit is not without restrictions and certain types of drugs may be difficult to access. This fact sheet provides basic information about prescription drug coverage under the Medicaid program and explains some of the more common problems experienced by beneficiaries.

### **What is the scope of coverage for prescription drugs under Medicaid?**

Under Title XIX of the Social Security Act, the federal government shares the State's cost of providing coverage for certain basic or mandatory [\(2\)](#) services to most categorically needy Medicaid beneficiaries. The State is also eligible to receive federal matching funds for certain optional services, including prescription drug coverage.

[\(3\)](#)

All states and the District of Columbia offer prescription drug coverage in their Medicaid programs.

Within broad federal guidelines, states have some flexibility to limit the amount, duration and scope of prescription drug coverage in their Medicaid programs. However, a state's ability to restrict or impose limitations on prescription drug coverage is not unbridled. There are four basic requirements:

*Amount, duration and scope.* Each covered service, including prescription drugs, must be sufficient in amount, duration, and scope to reasonably achieve its purpose.

[\(4\)](#)

The State may not arbitrarily deny or reduce the amount, duration, or scope of services to an otherwise eligible recipient solely because of the diagnosis, type of illness, or condition.

[\(5\)](#)

The State may place appropriate limits on a service based on such criteria as medical necessity or utilization control criteria.

[\(6\)](#)

*Comparability.* The services made available to any categorically needy individuals must not be less in amount, duration, or scope than those services made available to medically needy individuals. [\(7\)](#) Services made available to any individuals in the categorically needy or medically needy group must be equal in amount, duration and scope for all individuals within the group. [\(8\)](#)

*Statewideness.* The amount, duration and scope of coverage must be the same statewide, unless the State has received permission from the Secretary of HHS to waive this requirement.

*Freedom of Choice.* Generally, a Medicaid beneficiary is entitled to a free choice of participating providers. [\(9\)](#) However, at a State's request, the Secretary can waive this requirement and allow states to use alternative delivery systems, (e.g., managed care) and restrict Medicaid recipients to certain providers.

## **How do states limit access to prescription drugs?**

*Prescription limits.* To control utilization and costs, several states limit the number of prescriptions that a beneficiary can have filled per month, or per year. While many of these programs allow for exceptions, (e.g., in the case of life threatening illnesses) or provide some mechanism to allow for review and reconsideration, some do not.

Federal law allows states to impose limitations, with respect to all such drugs in a therapeutic class, on the minimum or maximum quantities per prescription or on the number of refills, if such limitations are necessary to discourage waste, and may address instances of fraud or

abuse by individuals in any manner authorized. [\(10\)](#)

*Cost-sharing.* Many states impose co-payments for prescription drugs, ranging from \$0.50 to \$5.00. Although the federal Medicaid statute allows states to impose "nominal" co-payments, certain restrictions apply. Some categories of recipients, including those under 18 years of age, pregnant women, specified residents of medical institutions and patients needing emergency services cannot be charged co-payments. Some categories of services, such as family planning services, are also exempt. Finally, the regulations prohibit any provider from denying a service due to a beneficiary's inability to pay a co-payment.

*Restricting Access to Specified Drugs* States are permitted to exclude from coverage or otherwise restrict access to the following types of drugs or agents:

- Anorexia, weight loss, or weight gain drugs
- Fertility drugs
- Drugs used for cosmetic purposes or hair growth
- Drugs used for the symptomatic relief of cough and colds
- Drugs used to promote smoking cessation
- Prescription vitamins and minerals, except prenatal vitamins and fluoride preparations
- Nonprescription drugs
- Covered outpatient drugs which the manufacturer seeks to require as a condition of sale that associated tests or monitoring services be purchased exclusively from the manufacturer or its designee.
- Barbituates
- Benzodiazepines [\(11\)](#)

*Prior authorization.* States are allowed to require prior approval of a prescription drug before it is dispensed for any medically accepted indication but only if the system for providing such approval --

(1) provides responses by telephone or other telecommunication device within 24 hours of a request for prior authorization; and

(2) except with respect to restricted drugs, provides for the dispensing of at least 72- hour supply of a covered outpatient drug in an emergency situation. [\(12\)](#)

A prior authorization process that delays access to medically necessary prescription drugs may violate the requirement that states furnish assistance to eligible individuals "with reasonable promptness." [\(13\)](#)

### **What are drug formularies and how do they affect access?**

A drug formulary is a list of medications that identifies the drugs that an insurer will cover. States (and private health insurers) use drug formularies to restrict access to certain types of drugs or classes of drugs, largely to control costs. Under the Medicaid program, certain restrictions apply:

- The formulary must be developed by a committee consisting of physicians, pharmacists, and other appropriate individuals appointed by the Governor of the State or the State's drug use review board.
- The formulary includes the covered outpatient drugs of any manufacturer who has entered into and complies with a Medicaid rebate agreement (see below).
- A covered outpatient drug may be excluded with respect to a specific disease or condition for an identified population only if, based on the drug's labeling, the excluded drug does not have a significant, clinically meaningful therapeutic advantage (in terms of safety, effectiveness, or clinical outcome) over other drugs included in the formulary, and there is a written explanation (available to the public) of the basis for the exclusion.
- The State's Medicaid plan permits coverage of a drug excluded from the formulary pursuant to a prior authorization program that complies with the requirements of the Medicaid statute.
- The formulary meets other requirements imposed by the Secretary. [\(14\)](#)

### **What is the Drug Rebate Program?**

The Medicaid drug rebate program requires that drug manufacturers pay a rebate to state Medicaid programs for each of the manufacturer's pharmaceutical products. The rebate is the

higher of a basic percentage rebate or a rebate equivalent to the best price the manufacturer offers a non-government customer. The program essentially requires pharmaceutical companies to give discounts to state Medicaid programs as a condition of receiving Medicaid payments. [\(15\)](#)

### **How has managed care affected access to and utilization of prescription drugs in the Medicaid program?**

The exponential growth of managed care in Medicaid has raised a number of problems associated with prescription drug benefits. Among the major areas of concern for beneficiaries are:.

- *Increased Utilization Controls:* The prescription drug benefit is subject to more utilization controls. Beneficiaries in managed care may face more limitations on the number of prescription drugs and the number of refills permitted without prior authorization.
- *Decreased freedom of choice:* HMOs generally require beneficiaries to get their prescriptions filled at pharmacies that have entered into a contract with the managed care plan. These pharmacies may be large chains that can afford to offer discounted prices to the plan. Thus, some beneficiaries may find that they no longer can get their prescriptions filled at their neighborhood drug store and may have to travel farther to obtain their medications.
- *Restrictive definitions of medical necessity.* Contracts between state Medicaid agencies and managed care plans often fail to specify a sufficiently broad definition of medically necessary care. If definitions of medical necessity are written or are applied too narrowly, the managed care plan may be denying payment for prescription drugs inappropriately. [\(16\)](#)
- *Payment denials for medications prescribed by out-of-plan providers:* In some states, the managed care plan is responsible for paying for all prescription drugs, even when services have been carved out of the plan (e.g., mental health services) or when services may be obtained out of plan (e.g. family planning services). This has resulted in reported conflicts over who is responsible for payment, payment denials, concerns about continuity of care and violations of patient confidentiality. [\(17\)](#)
- *Restrictive Drug Formularies:* Managed care companies save money by buying

pharmaceuticals in bulk and limiting coverage to only those drugs listed on their formulary. Formularies may be overly restrictive. Adequate inclusion of drugs used to control psychiatric illness, treat HIV/AIDS, or other chronic conditions is often most problematic. Managed care plans may also be resistant to adding new drugs to their formularies, even if the drugs are known to be effective.

Reports from both the commercial market and Medicaid managed care indicate that managed care plans will require providers to first use older, less expensive drugs on their formularies before allowing prescriptions for the newer. More effective drugs such as Clozaril to treat mental illness.

[\(18\)](#)

- *Decision Makers Lack Adequate Training to Determine Appropriate Prescription Drugs:* Advocates for people with disabilities and chronic conditions complain that decisions are made by health care professionals lacking sufficient knowledge of drug therapies and that both drug formularies and the companies that manage them have financial incentives to use (and pressure physicians to use) less effective drugs because they are cheaper.

- *Failure to Coordinate Medication Regimens Between Primary Care Provider and Carve-Out* : Coordination between carve-out providers and other providers is lacking and appears to be particularly problematic in the area of prescription drugs. [\(19\)](#)

- *Excessive Reliance on Drug Therapies:* Managed care companies sometimes rely too heavily on drug therapy. Not only do they limit coverage for psychotherapy, they often pay psychiatrists more per hour to supervise drug treatment than to provide counseling. This preference for drug therapy extends to both adults and children. [\(20\)](#)

### How has litigation affected access to prescription drugs in the Medicaid program?

Litigation has served as an important tool to secure medically necessary prescription drugs for Medicaid beneficiaries and to challenge state policies and practice that go too far in restricting access. For example:

- In *Vissor v. Taylor*, [\(21\)](#) the plaintiff successfully challenged the state's refusal to cover Clozaril in its prescription drug program. The court held that the state's refusal to cover Clozaril in its prescription drug program violated Medicaid regulations because it was an arbitrary reduction in the scope of services and a denial of medically necessary treatment.

- In *Dodson v. Parham*, [\(22\)](#) the plaintiffs successfully challenged the state's restrictive formulary because it failed to provide services in sufficient amount, duration, and scope to achieve the purposes of the Act.

- In *Weaver v. Regan*, [\(23\)](#) the court ruled that Missouri could not deny coverage of AZT for

AIDS patients who are Medicaid eligible and whose physicians have certified that AZT is medically necessary.

- In *Sobky v. Smoley*, [\(24\)](#) plaintiffs challenged the state's practice of allowing its counties to determine whether and in what amount to provide Medi-Cal funded methadone maintenance treatment services. The court ruled that the State's practice violated the comparability provisions of the Medicaid statute.

## **Additional Resources**

National Health Law Program, *An Advocate's Guide to the Medicaid Program* (1993) (updated edition forthcoming, Summer 1999).

Families USA and the National Health Law Program, *Meeting the Needs of People with Chronic and Disabling Conditions in Medicaid Managed Care* (January 1998).

National Health Law Program, *A Guide to Medi-Cal Managed Care for People with Developmental Disabilities, their Families and Professionals* (April 1999)

## **Endnotes**

1. Health Care Financing Administration, 2082 Data, 1997.

2. Basic or mandatory Medicaid services generally include inpatient hospital services; outpatient hospital services; prenatal care; vaccines for children; physician services; nursing facility services for persons aged 21 or older, family planning services, rural health clinic services, home health care for person eligible for skilled nursing services; laboratory and x-ray services;

pediatric and family nurse practitioner services; nurse midwife services; Federally-qualified health center services and early and periodic screening, diagnosis and treatment (EPSDT) services for children under age 21. 42 U.S.C. §§ 1396a(a)(1)(A); 1396d(a); 42 C.F.R. § 440.210.

3. Included among the optional services are: home health services, dental services, diagnostic services, clinic services, intermediate care facilities for the mentally retarded, prescription drugs and prosthetic devices, rehabilitation and physical therapy services, hospice care, case management services, respiratory care services, and alcohol and drug treatment. 42 U.S.C. §§ 1396a(a)(1)(A)(ii); 1396d(a)(6)-(16), (18); 42 C.F.R. §§436.300-.330.

4. 42 C.F.R. § 440.230(b).

5. 42 C.F.R. § 440.230(c).

6. 42 C.F.R. § 440.230(d).

7. 42 U.S.C. § 1396a(a)(10)(B)(ii); 42 C.F.R. § 440.240(a).

8. 42 U.S.C. §§ 1396a(a)(10)(B)(i), 1396a(a)(10)(C); 42 C.F.R. § 440.240(b).

9. 42 U.S.C. § 1396a(a)(23).

10. 42 U.S.C. § 1396r(8)(d)(6).

11. 42 U.S.C. § 1396r-8(d)(2).



12. 42 U.S.C. § 1396r-8(d)(5).

13. 42 U.S.C. § 1396a(a)(8).

14. 42 U.S.C. 1396r-8.

15. 42 U.S.C. §1396r-8.

16. Sara Rosenbaum, Peter Shin, et al., *Negotiating the New Health Care System: A Nationwide Study of Medicaid Managed Care Contracts, Vol II, Part II*, Center for Health Policy Research, the George Washington University Medical Center, Feb. 1997.

17. For example, in Pennsylvania, although the responsibility for payment of prescription drugs ordered by the behavioral health carve-out rests with the enrollee's mainstream HMO, some of the drugs prescribed are not on the HMO's formulary and thus are not covered. Ann Torregrossa, Pennsylvania Health Law Project, Philadelphia, PA, personal communication, September 4, 1997, in Geraldine Dallek, Claudia Schlosberg et al, *Meeting the Needs of People with Chronic and Disabling Conditions in Medicaid Managed Care*, Families USA and the National Health Law Program, 1998, (hereinafter "*Meeting the Needs*"), at 13.

18. Val Pendergrast, "House of Cards," Metro Pulse (Knoxville, TN), April 17-23, 1997; *Medicaid Reform and Managed Care*

19. In Utah, for example, physicians in the carve-out failed to coordinate their medication regimens with the clients' primary care physicians or HMOs. See Utah Prepaid Mental Health Plan - 1915(b) Waiver Renewal Request, submitted by the Division of Health Care Financing-Utah Department of Health, Salt Lake City, March 15, 1997, to the Office of Managed Care, Health Care Financing Agency, U.S. Department of Health and Human Services,

*in Meeting the Needs*  
at 14.

20. During the three years following implementation of Massachusetts's Medicaid behavioral managed care plan, total expenditures for mental health clinic medication increased almost three-fold (295 percent). During the same period, beneficiaries experienced large cutbacks in mental health clinic and hospital outpatient therapy. Susan Fendell, "Mental Health Managed Care: Expansion to DMH Acute Care and Medicaid Update," *Advisor*, Mental Health Legal Advisors Committee, Boston, MA, (Fall 1996):12-15;

*see also*

"Managed Care's Focus on Psychiatric Drugs Alarms Many Doctors,"

*The Wall Street Journal*

, December 1, 1995 (Use of Ritalin, a stimulant prescribed to children with attention deficit disorder, is on the rise. Child health specialists are also reporting increased use of Prozac and other antidepressants for young children).

21. 756 F. Supp. 501, 507 (D. Kan. 1990).

22. 427 F.Supp. 97, 104-5(N.D. Ga. 1977).

23. 886 F.2d 194, 197-200 (8<sup>th</sup> Cir. 1989), *reh'g denied* (Nov 6, 1989).

24. 855 F. Supp. 1123, 1126-27 (E.D. Cal.,1994).