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Medicaid and Viagra: Restoring Potency to an Old Program

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MEDICAID AND VIAGRA: RESTORING POTENCY TO AN OLD PROGRAM?

David F. Chavkin[†]

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I. INTRODUCTION

WHEN THE MEDICAID PROGRAM was enacted in 1965,¹ the original statutory scheme envisioned a rapid transition to a "comprehensive" scope of services for broad categories of individuals.² This "comprehensiveness" requirement was added to the Social Security Act "in order to encourage the continued development in the States of a broadened and more liberalized medical assistance program so that all persons who met the State's test of need . . . [would] receive the medical care which they need by 1975."³

In 1969, the "comprehensiveness" requirement was reconsidered by Congress. In response to cries of impoverishment from the various states,⁴ the Senate Finance Committee recommended indefinite suspension of this requirement.⁵ However, the Finance Committee recommendation was rejected in favor of a compromise whereby section 1903(e) was suspended in op-

¹ Social Security Amendments of 1965, Pub. L. No. 89-97, §§ 1901-05, 79 Stat. 286, 343-52 (1965).

² Social Security Act of 1965, Pub. L. No. 89-97, § 1903(e), 79 Stat. 286, 350-51 (1966), *repealed by* Social Security Amendments of 1972, Pub. L. No. 92-603, § 230, 86 Stat. 1410 (1972). Section 1903(e) provided as follows:

The Secretary shall not make payments under the preceding provisions of this section to any State unless the State makes a satisfactory showing that it is making efforts in the direction of broadening the scope of the care and services made available under the plan and in the direction of liberalizing the eligibility requirements for medical assistance, with a view toward furnishing by July 1, 1975, comprehensive care and services to substantially all individuals who meet the plan's eligibility standards with respect to income and resources, including services to enable such individuals to attain or retain independence or self-care.

42 U.S.C. § 1396b (1965), *reprinted in* 1969 U.S.C.C.A.N. 1077, 1080.

The federal guidelines interpreting this section stated that, "[c]omprehensive care includes all preventive, diagnostic, curative and rehabilitative services or goods furnished, prescribed or ordered by a recognized practitioner of the healing arts within the scope of his practice." U.S. DEP'T OF HEALTH, EDUC. & WELFARE, HANDBOOK OF PUBLIC ASSISTANCE ADMINISTRATION, SUPPLEMENT D: MEDICAL ASSISTANCE PROGRAMS D-5142 (1966). The "comprehensiveness" requirement was repealed by section 230 of the Social Security Amendments of 1972, Pub. L. No. 92-603, 86 Stat. 1410 (1972).

³ Report of Ways and Means Committee on the Social Security Amendments of 1965, H.R. REP. NO. 89-213, at 74 (1965).

⁴ *See* S. REP. NO. 91-222 (1969), *reprinted in* 1969 U.S.C.C.A.N. 1077, 1081-82 (reporting comments of State Governors).

⁵ *See id.*

eration for two years (until July 1, 1971),⁶ and the time within which the participating states would be required to achieve a comprehensive medical assistance program was extended for two years (until July 1, 1977).⁷

In 1971, New York became one of the first states to significantly cut back benefits under the Medicaid program.⁸ After an order was issued temporarily restraining the proposed cutbacks because of the failure of the State to obtain prior approval from the Secretary of Health, Education, and Welfare,⁹ the State ob-

⁶ See Pub. L. No. 91-56, § 2(b), 83 Stat. 99, 99 (1969). "The provisions of section 1903(e) of the Social Security Act shall not apply for any period prior to July 1, 1971. In performing his functions under title XIX of the Social Security Act, the Secretary of Health, Education and Welfare shall issue regulations and give advice to the States consistent with the preceding sentence." *Id.*

⁷ Section 2(a) of Pub. L. No. 91-56, 83 Stat. 99 (1969), delayed the effective date of section 1903(e) of the Social Security Act by substituting "1977" for "1975" in subsection (e). See *id.*

⁸ On April 14, 1971, New York State amended its Social Services Law by enacting Chapters 113 and 131 of the Laws of 1971, to be effective May 15, 1971. As described by U.S. District Judge Cooper:

The new law sought to significantly and drastically infringe upon the availability of medical assistance by reducing the amount of income and resources an individual may have and hold and still remain eligible for Medicaid. Additionally, many medical services previously supplied would be eliminated for that category of recipients described as "medically needy," i.e. those individuals with incomes and resources above the cash public assistance level but below the level necessary to purchase such essential medical services [such as dental care, prescribed drugs, and eye-glasses].

Bass v. Richardson, 338 F. Supp. 478, 481 (S.D.N.Y. 1971).

Over the next 20 years, state after state would alternately cutback and expand their Medicaid programs to deal with projected budget deficits, often without real thought of the true financial consequences of cutbacks and their impact on the health of Medicaid beneficiaries. See David F. Chavkin, *Florida Medicaid Reform: Less is Not Always Cheaper*, 14 CLEARINGHOUSE REV. 324 (1980) (describing the cost-inefficiency of cutbacks implemented in Florida in the 1970s).

⁹ In *Bass v. Rockefeller*, 331 F. Supp. 945 (S.D.N.Y. 1971), Judge Tenney ruled that prior approval of the Secretary of Health, Education, and Welfare was an absolute prerequisite to amendments effecting state plan reductions under section 1902(d) of the Social Security Act, 42 U.S.C. § 1396a(d). Section 1902(d) was added to the Social Security Act by section 2(d) of Pub. L. No. 91-56, effective August 9, 1969. Section 1902(d) of the Social Security Act provided as follows:

Whenever any State desires modification of the State plan for medical assistance so as to reduce the scope or extent of the care and services provided as medical assistance under such plan, or to terminate any of such care and services, the Secretary shall, upon application of the State, approve any such modification if the Governor of such State certifies to the Secretary that —

tained approval from the Secretary and pursued the cutbacks. The approval by the Secretary and the underlying cutbacks were then challenged as violative of section 1902(d) (the "maintenance of effort" requirement) and section 1903(e) (the "comprehensiveness" requirement).¹⁰

-
- (1) the average quarterly amount of non-Federal funds expended in providing medical assistance under the plan for any consecutive four-quarter period after the quarter in which such modification takes effect will not be less than the average quarterly amount of such funds expended in providing such assistance for the four-quarter period which immediately precedes the quarter in which such modification is to become effective,
 - (2) the State is fully complying with the provisions of its State plan (relating to control of utilization and costs of services) which are included therein pursuant to the requirements of subsection (a) (30), and
 - (3) the modification is not made for the purpose of increasing the standard or other formula for determining payments for those types of care or services which, after such modification, are provided under the State plan,

and if the Secretary finds that the State is complying with the provisions of its State plan referred to in clause (2); except that nothing in this subsection shall be construed to authorize any modification in the State plan of any State which would terminate the care or services required to be included pursuant to subsection (a) (13) [sic] Any increase in the formula or other standard for determining payments for those types of care or services which, after such modification, are provided under the State plan shall be made only after approval by the Secretary.

Social Security Act of 1969, Pub. L. No. 91-56, § 2(d). Section 1902(d) was shortly thereafter repealed by section 231 of the Social Security Amendments of 1972, Pub. L. No. 92-603 (1972). *Bass v. Rockefeller* was subsequently dismissed as moot when the Secretary approved the cutback. See *Bass v. Richardson*, 338 F. Supp. 478, 481-82 (S.D.N.Y. 1971) (describing the prior history of the dispute).

¹⁰ The "maintenance of effort" requirement provided as follows:

(d) Whenever any State desires a modification of the State plan for medical assistance so as to reduce the scope or extent of the care and services provided as medical assistance under such plan, or to terminate any of such care and services, the Secretary shall, upon application of the State, approve any such modification if the Governor of such State certifies to the Secretary that -

- (1) the average quarterly amount of non-Federal funds expended in providing medical assistance under the plan for any consecutive four-quarter period after the quarter in which such modification takes effect will not be less than the average quarterly amount of such funds expended in providing such assistance for the four-quarter period which immediately precedes the quarter in which such modification is to become effective. . . .

42 U.S.C. § 1396a(d)(1), added by Pub. L. No. 91-56, § 2(d) (1969), repealed by Social Security Amendments of 1972, Pub. L. No. 92-603, § 231 (1972).

By the time that the case was heard by the district judge, after July 1, 1971, section 1903(e) was effective once again.¹¹ As noted by Judge Cooper:

It has now come to pass that the Secretary must make *two* independent findings before any reduced payments can be effected. He must first find that the State "*is fully* complying with the provisions of its State plan" in § 1902(d)(2); secondly, and before he may give approval, he must find that the State's showing is "satisfactory" that any such reduction, if effected, is fully in accordance with § 1903(e). Each finding is reviewable, and each finding was, in all probability, unwarranted in this case.¹²

The burden imposed by section 1903(e), the "comprehensiveness" requirement, proved to be fatal to the State's case.¹³ As noted by the Court, "[p]articularly in the case of a reduction, the State has a heavy burden under § 1903(e) to show that it in fact is making efforts to broaden the scope of care and services and to achieve the comprehensive goals of substantially full coverage."¹⁴ The Court then concluded that the State of New York had not met that burden:

The record is absolutely barren of facts to indicate in any way that New York State has any intention by legal commitments or other means of restoring these cutbacks before July 1, 1977 Even the most solemn of promises is insufficient here without precise legislature commitment of at least sources of funds, if not the actual funds.¹⁵

It should not have been surprising that section 1903(e) would be the subject of future congressional action. As costs of the Medicaid program increased along with health care costs

¹¹ See Social Security Act of 1965, Pub. L. No. 89-97, § 1903(e), 79 Stat. 286, 350-51 (1966), *repealed by* Social Security Amendments of 1972, Pub. L. No. 92-603, § 230, 86 Stat. 1329, 1410 (1973) (referencing § 1903(e) of the Social Security Act of 1965).

¹² *Bass v. Richardson*, 338 F. Supp. 478, 485 (S.D.N.Y. 1971).

¹³ See *id.* at 489.

¹⁴ *Id.* at 485 (citation omitted).

¹⁵ *Id.* at 489.

generally, state budgets were increasingly strained.¹⁶ In 1972, only a year after the decision in *Bass v. Richardson*, section 1903(e) was repealed completely, effective October 30, 1972.¹⁷ After being suspended and delayed, the requirement of movement towards comprehensive care and services in state Medicaid programs was eliminated.

Since that date, we have seen an increasing trend on the part of Congress to turn Medicaid from a categorical grant program into a block grant program.¹⁸ Under a block grant model, state administration would be subject to minimal supervision by the federal government and wide variation in spending priorities would likely be reflected in state plans. By contrast, in the existing categorical grant program model, states complain of micro-management by the federal government and of federal barriers to state innovation.¹⁹ It is against this political and legal

¹⁶ Despite the repeal of section 1903(e) and its "comprehensiveness" requirement in 1972, the problem of skyrocketing Medicaid costs would only increase in severity in the years ahead. As the total number of Medicaid recipients increased marginally from 17.6 million to 21.6 million from 1972 to 1980, the total payments made to health care providers nearly quadrupled from \$6.3 million to \$23.3 million. U.S. DEP'T OF HEALTH & HUM. SERV., HEALTH UNITED STATES: 1999, table 137 at 310 (1999).

¹⁷ See Social Security Amendments of 1972, Pub. L. No. 92-603, § 230, 86 Stat. 1329, 1410 (1972).

¹⁸ The congressional efforts were exemplified in several bills. See Welfare and Medicaid Responsibility Exchange Act of 1995, S. 140, 104th Cong. (1995) (noting that bill was sponsored and introduced by Sen. Kassebaum on Jan. 4, 1995 "[t]o shift financial responsibility for providing welfare assistance to the States and shift financial responsibility for providing medical assistance under title XIX of the Social Security Act to the Federal Government, and for other purposes"); see also Medicaid Flexibility Act of 1995, S. 844, 104th Cong. (1995) (sponsored and introduced by Sen. Ashcroft on May 23, 1995 "[t]o replace the Medicaid Program with a block grant to the States, and for other purposes"); Balanced Budget Reconciliation Act of 1995, H.R. 2491, 104th Cong. (1995) (proposing to transform the Medicaid program into a new Medicaid program in Title VII of the Act; legislation was sponsored and introduced by Rep. Kasich on Oct. 17, 1995); 141 CONG. REC. H8308, H8308 (1995) (providing "[a] bill to amend the Public Health Service Act and the Social Security Act to improve the access of rural residents to quality health care by consolidating various categorical programs into a single program of grants to the States, and for other purposes") (sponsored and introduced by Rep. Williams); Welfare and Medicaid Reform Act of 1996, H.R. 3734, 104th Cong. (1996) (sponsored and introduced by Rep. Kasich on June 27, 1996 to terminate the existing Social Security Act welfare and medical assistance grant-in-aid programs and establish block grants for temporary welfare assistance and medical assistance).

¹⁹ See *The Federalism Act of 1999: Hearings on H.R. 2245 Before the Subcomm. on Nat'l Econ. Growth, Natural Resources, and Regulatory Affairs of the House Comm. on Gov't Reform*, 106th Cong. 65-75 (1999) (prepared statement of

backdrop that the recent dispute regarding Medicaid coverage of Viagra has played out.

II. THE ADVENT OF VIAGRA²⁰

Erectile dysfunction²¹ affects approximately five percent of all men at the age of 40.²² Prevalence increases with age and 15 percent to 25 percent of men 65 years of age and older are affected.²³ Moreover, the prevalence of erectile dysfunction correlates directly with several age-related diseases.²⁴

Prior to the advent of Viagra, erectile dysfunction was managed with mixed success through psychotherapy,²⁵ intracavernosal injection therapy,²⁶ vacuum constriction devices,²⁷

Raymond C. Scheppach, Executive Director, on behalf of the National Governors' Ass'n). However, the frequent claim that states are laboratories for health care reform impeded by the federal government has its detractors. See Fernando R. Laguarda, Note, *Federalism Myth: States as Laboratories of Health Care Reform*, 82 GEO. L.J. 159 (1993).

²⁰ See generally AMERICAN PHARMACEUTICAL ASS'N, NEW PRODUCT BULLETIN: VIAGRA™ (SILDENAFIL) (1998).

²¹ The term "erectile dysfunction" refers to the consistent inability to achieve or maintain an erection sufficient for satisfactory sexual performance. See NIH Consensus Development Panel on Impotence, *Impotence*, 270 JAMA 83, 83 (1993). See generally John D. McConnell & Jean D. Wilson, *Impotence*, in HARRISON'S PRINCIPLES OF INTERNAL MEDICINE 286-89 (Anthony S. Fauci et.al. eds., 14th ed. 1998).

²² See NIH Consensus Development Panel on Impotence, *supra* note 21, at 84.

²³ See *id.*

²⁴ See Henry A. Feldman et al., *Impotence and Its Medical and Psychosocial Correlates: Results of the Massachusetts Male Aging Study*, 151 J. UROLOGY 54 (1994) (finding that certain medical conditions and diseases are significantly associated with prevalence of erectile dysfunction in older men).

²⁵ See NIH Consensus Development Panel on Impotence, *supra* note 21, at 87; see also A.J. Riley & L. Athanasiadis, *Impotence and Its Non-Surgical Management*, 51 BRIT. J. CLINICAL PRAC. 99 (1997) (discussing sex therapy as the psychotherapeutic approach of choice).

²⁶ The term "intracavernosal injection therapy" refers to the injection of a vasoactive agent into the corpora cavernosa of the penis to produce penile erection. See Luis Garcia-Reboll et al., *Drugs for the Treatment of Impotence*, 11 DRUGS & AGING 140, 140-41 (1997); Drogo K. Montague et al., *Clinical Guidelines Panel on Erectile Dysfunction: Summary Report on the Treatment of Organic Erectile Dysfunction*, 156 J. UROLOGY 2007 (1996) (outlining effective treatments for impotence); Douglas M. Dewire, *Evaluation and Treatment of Erectile Dysfunction*, 53 AM. FAM. PHYSICIAN 2101, 2105 (1996).

²⁷ Vacuum constriction devices are hollow cylinders with a movable rubber ring or band and a pump mechanism. The cylinder is lubricated and placed over the penis, creating an airtight seal. The pump is used to generate a vacuum inside the

hormonal therapy,²⁸ penile prostheses,²⁹ and other therapies.³⁰ Viagra³¹ was the first oral therapy to be approved for the treatment of male erectile dysfunction.³² It was approved by the

cylinder and the negative pressure results in increased arterial blood flow and penile erection. The rubber ring is then rolled from the cylinder to the base of the penis. Blood is trapped within the penis by the constriction of the rubber ring, producing a rigid erection. *See* Dewire, *supra* note 26, at 2105; K. Allen Greiner & John W. Weigel, *Erectile Dysfunction*, 54 AM. FAM. PHYSICIAN 1675, 1680 (1996).

²⁸ Androgen replacement therapy may be indicated if erectile dysfunction is the result of primary or secondary testicular failure, both of which are characterized by low serum testosterone concentrations. *See* NIH Consensus Development Panel on Impotence, *supra* note 21, at 87; Dewire, *supra* note 26, at 2104.

²⁹ A semi-rigid, malleable or inflatable prosthetic device may be surgically implanted in the penis. *See* Greiner & Weigel, *supra* note 27, at 1681; *see also* Montague et al., *supra* note 26, at 2008.

³⁰ Other therapies include vascular surgery, intraurethral administration of alprostadil formulated as suppositories, and topical administration of alprostadil, papaverine, nitroglycerin, or minoxidil. *See generally* Harin Padma-Nathan et al., *Treatment of Men with Erectile Dysfunction with Transurethral Alprostadil*, 336 NEW ENG. J. MED. 1 (1997); Greiner & Weigel *supra* note 27, at 1680-81; PHYSICIANS' DESK REFERENCE 2381-84, 2418-21, 3082, 3143-46 (David W. Sifton ed., 54th ed. 2000); Edward D. Kim & Larry I. Lipshultz, *Advances in the Treatment of Organic Erectile Dysfunction*, HOSP. PRAC., Apr. 15, 1997, at 101.

³¹ Viagra is the trademark of Pfizer, Inc. Viagra is the citrate salt of sildenafil, a selective inhibitor of cyclic guanosine monophosphate (CGMP)-specific phosphodiesterase type 5 (PDE5). *See* Pfizer, Inc., *U.S. Product Prescribing Information* (visited July 8, 1999) <<http://www.pfizer.com/hml/pi/s/viagrapi.html>>. In addition to the active ingredient (sildenafil citrate), each tablet contains the following inactive ingredients: microcrystalline cellulose, anhydrous dibasic calcium phosphate, croscarmellose sodium, magnesium stearate, hydroxypropyl methylcellulose, titanium dioxide, lactose, tracetin, and FD & C Blue #2 aluminum lake. *See id.*

³² Sexual stimulation is still required for an erection because sildenafil does not have a direct relaxant effect on smooth muscle. In the absence of sexual stimulation, sildenafil has no effect. *See* *Viagra.com* (last modified Jan. 2000) <http://www.viagra.com/professionals/pro_pack_insert.asp> (describing the nature, pharmacology, effects, and risks of Viagra as indicated in the package insert). This point is emphasized in the *Patient Summary of Information About Viagra* published by Pfizer, Inc. In answering the question, "What is Viagra?", the *Patient Summary* explains:

VIAGRA is a pill used to treat erectile dysfunction (impotence) in men. It can help many men who have erectile dysfunction get and keep an erection when they become sexually excited (stimulated). You will not get an erection just by taking this medicine. VIAGRA helps a man with erectile dysfunction get an erection only when he is sexually excited.

Pfizer Inc., *Patient Summary of Information About Viagra*® (*sildenafil citrate*) *Tablets* (visited July 8, 1999) <http://www.viagra.com/consumer/prod_info.htm>. It will hardly be the last prescription medication for treatment of erectile dysfunction. *See* Geoffrey Cowley, *Looking Beyond Viagra*, NEWSWEEK (Japan-Korea), Apr. 24, 2000, at 50 (describing progress towards marketing of additional anti-impotence drugs).

Food and Drug Administration on March 27, 1998³³ and has been an enormously successful product for Pfizer.³⁴ That success reflects the pent-up demand for a simple treatment of a condition that not only affects millions of men and their partners,³⁵ but one that goes to the core identity of many men.³⁶ The stage was set for a confrontation between the states and the federal government over coverage of Viagra in the major health insurance program for the poor—the Medicaid program.³⁷

³³ See Determination for Regulatory Review Period for Purposes of Patent Exclusion; Viagra, 64 Fed. Reg. 4115 (1999) (establishing the regulatory review period for purposes of patent extension for Viagra).

³⁴ Viagra's worldwide sales for the first quarter of 1999 were \$193 million. First launched in the U.S. in April 1998, more than 9 million prescriptions had been written for more than 4 million patients in the U.S. alone. Viagra had been approved in 77 countries and launched in 62 through the end of the quarter. See Pfizer Inc., 2000 First Quarter Earnings Release: Pfizer 1st Quarter Total Revenues of \$3,927 Million Up by 29 Percent (issued Apr. 15, 1999) (visited Oct. 10, 2000) <<http://www.pfizer.com/pfizerinc/investing/annual/earnings/1999Q1earnpr.html>>.

For a discussion of the development and introduction of Viagra, see Peter Carlson, *Potent Medicine: A Year Ago, Viagra Hit the Shelves and the Earth Moved. Well, Sort of*, WASH. POST, Mar. 26, 1999, at C1 (describing success of Viagra from a patient's and Pfizer's standpoints).

³⁵ By the first quarter of 1999, one in three U.S. doctors had written a prescription for Viagra, "including over 95 percent of urologists, 70 percent of cardiologists and half of all primary care physicians." *Pfizer 2000 First Quarter Earnings Release*, *supra* note 34.

³⁶ In his testimony before the Pennsylvania House Health and Human Services Committee, Dr. Mike Magee, Senior Medical Advisor for Pfizer, described "stories of men who had downwardly spiraled as a result of erectile dysfunction; had marital difficulties, had problems on the job, had depression, had this condition affect their lives in a significant way." *Hearing on Access to Pharmaceutical Services in the Medical Assistance Program: Hearings Before the Pennsylvania House Comm. on Health & Hum. Serv.* (Oct. 8, 1998) at 9 (copy on file with author) [hereinafter Transcript of Pennsylvania Hearing] (statement of Dr. Mike Magee, Pfizer Senior Medical Advisor). Among the witnesses were Dr. Mike Magee, Senior Medical Advisor for Pfizer, and William Stayton, President of the American Association of Sex Educators, Counselors and Therapists and Adjunct Professor, University of Pennsylvania. See *id.* It is hardly a magic bullet for every instance of sexual dysfunction in an intimate relationship, however. See Lynne Lamberg, *New Drug for Erectile Dysfunction Boon for Many. "Viagravation" for Some*, 280 JAMA 867 (1998).

³⁷ Viagra is not the first anti-impotence treatment to raise the specter of widespread state noncompliance with Federal Medicaid standards. Starting in 1996, Alaska, Delaware, Idaho, Kentucky, North Carolina, South Dakota, Washington, and Wyoming excluded Medicaid coverage of Caverject. See *Idaho May Violate Federal Law for Denying Impotence Drug*, IDAHO STATESMAN, Jan. 2, 1998, at 5b. States argued unsuccessfully that Caverject came within the exclusion of drugs to treat infertility. See *id.* However, in language evocative of the dispute to come over Medicaid coverage of Viagra, the Health Care Financing Administration notified states that Caverject is not a fertility drug and that states must provide Medicaid coverage.

III. MEDICAID COVERAGE OF PRESCRIPTION DRUGS

Since the enactment of the Medicaid program in 1965, prescribed drugs have been a type of "medical assistance"³⁸ for which federal financial participation is available.³⁹ However, although prescribed drugs have been included within the Medicaid program, they have not been treated in the same way as physician services, hospital services, and many other forms of medical care.

The federal Medicaid statute distinguishes between "required" services that must be included in approved state plans for at least some categories of eligible beneficiaries and "optional" services that may be included.⁴⁰ Despite the critical role

Health Care Financing Admin., STATE MEDICAID DRUG REBATE PROGRAM RELEASE 55 (circa 1997-98) (on file with author); *see also Idaho May Violate Federal Law For Denying Impotence Drug, supra.*

³⁸ The term "medical assistance" is a term of art in the Medicaid program used to describe those goods and services for which federal financial participation is available when provided to eligible individuals. For example, section 1903(a)(1) of the Social Security Act provides that, "[f]rom the sums appropriated therefor, the Secretary . . . shall pay to each State which has a plan approved under this subchapter . . . (1) an amount equal to the Federal medical assistance percentage . . . of the total amount expended during such quarter as *medical assistance* under the State plan . . ." 42 U.S.C. § 1396b(a)(1) (1994) (emphasis added). Section 1905(a) of the Social Security Act provides as follows: "The term 'medical assistance' means payment of part or all of the cost of the following care and services . . . (12) prescribed drugs, dentures, and prosthetic devices; and eyeglasses prescribed by a physician skilled in diseases of the eye or by an optometrist, whichever the individual may select . . ." 42 U.S.C. § 1396d(a)(12) (1994).

³⁹ Pursuant to section 1905(b) of the Social Security Act, federal financial participation varies inversely with the per capita income in the state. Poorer states receive a higher federal matching rate (which cannot exceed 83 percent) and wealthier states receive a lower federal matching rate (which cannot be less than 50 percent). *See* 42 U.S.C. § 1396b(a), (b) (1994).

⁴⁰ Section 1902(a) of the Social Security Act provides that, "[a] State plan for medical assistance must - (10) provide - (A) for making medical assistance available, including at least the care and services listed in paragraphs (1) through (5), (17) and (21) of section 1396d(a) of this title, to [specified classes of beneficiaries] . . ." 42 U.S.C. § 1396a(a)(10) (1994 & Supp. III 1998). The so-called "required" care and services listed in these designated paragraphs include inpatient hospital services; outpatient hospital services; rural health clinic services; federally-qualified health center services; laboratory and x-ray services; nursing facility services; early and periodic screening, diagnostic, and treatment services; family planning services and supplies; physicians' services; medical and surgical services furnished by a dentist; services furnished by a nurse-midwife; and services furnished by a certified pediatric nurse practitioner or certified family nurse practitioner. *See* 42 U.S.C. § 1396d(a) (1994).

that prescribed drugs play in modern medical care, prescribed drugs are not among the enumerated "required" services and, therefore, historically did not even have to be included in state plans.⁴¹ Moreover, the federal regulations piggyback on the distinction between "required" and "optional" services in circumscribing the scope of state discretion in defining the "amount, duration, and scope"⁴² of these services.⁴³ As an "optional" service, prescribed drugs therefore historically could be limited

⁴¹ See 42 U.S.C. § 1396a(10)(A) (1994 & Supp. III 1998); see also 42 U.S.C. § 1396d(a)(12) (1994). As is evident from the list of "required" care and services, the term "required" does not necessarily reflect the medical necessity of the care and services. Prescribed drugs may be "required" in the sense of medical necessity but are "optional" in the sense of inclusion within a state plan. State plans have recognized this distinction and all states now include prescribed drugs as a covered service despite the fact that they are optional within a state plan.

⁴² This term comes from the statutory language governing the quantity of services that must be provided to Medicaid beneficiaries under an approved state plan. Section 1902(a) of the Social Security Act provides that, "[a] State plan for medical assistance must – (10) provide . . . (B) that the medical assistance made available to any individual described in subparagraph (A) – (i) shall not be less in *amount, duration, or scope* than the medical assistance made available to any other such individual, and (ii) shall not be less in *amount, duration, or scope* than the medical assistance made available to individuals not described in subparagraph (A)." 42 U.S.C. § 1396a(a)(10)(B) (1994 & Supp. III 1998) (emphasis added). These requirements are further defined in the implementing regulations. See 42 C.F.R. § 440.230 (1999).

⁴³ 42 C.F.R. § 440.230 (1999) provides as follows:
 Sufficiency of amount, duration, and scope.
 (a) The plan must specify the amount, duration, and scope of each service that it provides for –
 (1) The categorically needy; and
 (2) Each covered group of medically needy.
 (b) Each service must be sufficient in amount, duration, and scope to reasonably achieve its purpose.
 (c) The Medicaid agency may not arbitrarily deny or reduce the amount, duration, or scope of a *required* service under §§ 440.210 and 440.220 to an otherwise eligible recipient solely because of the diagnosis, type of illness, or condition.
 (d) The agency may place appropriate limits on a service based on such criteria as medical necessity or on utilization control procedures.
 (emphasis added). Subsection (c) only prohibits a state from limiting the amount, duration or scope of a required service based on the diagnosis, type of illness, or condition. Since prescribed drugs are not a required service, states may limit access to prescribed drugs consistent with this provision based on diagnosis, type of illness, or condition.

in ways that would not be permitted for other medically necessary care and services.⁴⁴

IV. THE ENACTMENT OF SECTION 1927

Section 1927 was added to the Social Security Act by the Omnibus Budget Reconciliation Act (OBRA) of 1990.⁴⁵ As is common in reconciliation bills, the Act included spending cuts to bring outlays within limits established by the budget resolution for that fiscal year.⁴⁶ The House of Representatives described the impact of section 1927 in the following language:

⁴⁴ This issue is discussed at greater length *infra* in Part IX.A. Some have argued that Congress should "adequately define the term 'medically necessary' for the purpose of Medicaid." Carole L. Stewart, Comment, *Mandated Medicaid Coverage of Viagra: Raising the Issues of Questionable Priorities, the Need for a Definition of Medicaid Necessity, and the Politics of Poverty*, 44 LOY. L. REV. 611, 625 (1998). At a time when Congress is considering so-called "Patient's Rights" bills to prevent insurance companies from second-guessing physician determinations of medical necessity, it seems far more appropriate to assign the role of defining "medical necessity" to physicians and other health professionals treating Medicaid patients. Of course, some of the reasons why commentators have proposed a federal definition flows from their hostility to such determinations of medical necessity as the performance of sex reassignment surgery for transsexual patients. *See id.* at 626 (characterizing coverage of gender reassignment surgery with public funds as an "absurd" result). Although the American Psychiatric Association and other professional groups have determined that gender reassignment surgery is an appropriate treatment for transsexualism, the lack of sympathy in certain camps for persons suffering from this disorder has made it an easy target despite the fact that courts have consistently held that federal law mandates such coverage in appropriate cases. *See AMERICAN PSYCHIATRIC ASS'N, DIAGNOSTIC AND STATISTICAL MANUAL OF MENTAL DISORDERS (DSM-IV) 532-38 (4th ed. 1994)* (discussing interest in gender-reassignment surgery for those with gender identity disorders); *see also* *Rush v. Parham* 625 F.2d 1150, 1156-58 (5th Cir. 1980) (invalidating the Georgia exclusion of gender reassignment surgery from Medicaid reimbursement); *Pinneke v. Preisser*, 623 F.2d 546 (8th Cir. 1980) (invalidating the Iowa exclusion of sex reassignment surgery from Medicaid reimbursement); *J.D. v. Lackner*, 145 Cal. Rptr. 570 (Ct. App. 1978) (requiring coverage of radical sex conversion surgery under Medicaid for treatment of transsexualism); *G.B. v. Lackner*, 145 Cal. Rptr. 555 (Ct. App. 1978) (rejecting the California characterization of gender reassignment surgery as cosmetic); *Doe v. State Dep't of Pub. Welfare*, 257 N.W.2d 816 (Minn. 1977) (rejecting the Minnesota exclusion of transsexual surgery from eligibility for medical assistance payments); *Denise R. v. Lavine*, 347 N.E.2d 893 (N.Y. 1976) (upholding the denial of female sexual conversion surgery as not medically necessary in this instance).

⁴⁵ Pub. L. No. 101-508, § 4401, 104 Stat. 1388, 1388-143-159 (1990) (codified as amended at 42 U.S.C.A. § 1396r-8 (West 1992 & Supp. 2000)). Section 4401 provided for reductions in Medicaid spending by altering reimbursement for prescription drugs.

⁴⁶ *See* David F. Chavkin & Yvette Hutchinson, *A Health Advocate's Guide to the Federal Budget Process*, 15 CLEARINGHOUSE REV. 324, 332 (1981) (noting that

The Budget Resolution also apparently assumes reductions of \$2.38 billion in Medicaid outlays over the period FY 1991 through 1995. The Committee bill would achieve these savings primarily by *reforming the purchase of prescription drugs by the States* and by requiring the States, where cost-effective, to purchase employer group health coverage on behalf of Medicaid beneficiaries.⁴⁷

Of the \$2.38 billion reduction in Medicaid outlays over the period 1991 to 1995, \$2.105 billion was attributed to the changes in Medicaid reimbursement for prescription drugs.⁴⁸

Like many provisions in omnibus reconciliation bills, section 1927 did not originate in the 1970 Act. Efforts to control prescription drug prices in the Medicaid program had been in the works for many years.⁴⁹ Almost as soon as he was elected to the Senate, David Pryor of Arkansas began fighting to control prescription drug prices because of their devastating effect on the elderly.⁵⁰ In 1990, Senator Pryor introduced the Medicaid

committees propose specific measures to bring spending within limits). As is also common, however, it also included spending increases in certain areas. *See* Omnibus Budget Reconciliation Act of 1990, Pub. L. No. 101-508, 104 Stat. 1388, 1388-166-69 (increasing payments to improve child health through mandatory continuation of benefits throughout pregnancy or first year of life and by adjusting payments for hospital services furnished to low income children under the age of 6 years); *see also id.* at 1388-170-71 (discussing State Medicaid matching payments through voluntary contributions and State taxes).

⁴⁷ H.R. REP. NO. 101-881, at 65 (emphasis added) (Report of the Committee on the Budget), *reprinted in* 1990 U.S.C.C.A.N. 2017, 2077. The final version of section 1927 largely reflected the provisions of the House bill. *See* H.R. REP. NO. 101-964, at 832 (1990), *reprinted in* 1990 U.S.C.C.A.N. 2526, 2537 (Omnibus Budget Reconciliation Act of 1990: Conference Report to Accompany H.R. 5835) (stating, "[t]he conference agreement includes the House bill with amendments to prohibit the Secretary and the States from reducing drug product reimbursement levels and dispensing fees for pharmacists from the levels in effect August 1, 1990 through March 30, 1995").

⁴⁸ *See* H.R. REP. NO. 101-881, at 68.

⁴⁹ Reconciliation bills often include measures proposed independently as bills in prior Congresses that could not be passed as separate enactments. By combining these provisions in an omnibus bill, they can often be passed either as *stealth* measures that go largely undetected through the legislative process or as compromise provisions traded by the chairs or ranking members of authorizing committees.

⁵⁰ As Chair of the Senate Aging Committee, Senator Pryor held numerous hearings to highlight this issue for legislative action. *See Cost of Prescription Drugs*, 136 CONG. REC. S5811 (daily ed. May 8, 1990) (statement of Sen. Pryor); *see also Drug Manufacturers: Making Profits on Backs of Poor*, 136 CONG. REC. S10,497-04 (daily ed. July 25, 1990) (statement of Sen. Pryor); *The High Cost of Prescription*

Anti-Discriminatory Drug Price and Patient Benefit Restoration Act in the 101st Congress.⁵¹ In introducing this bill, Senator Pryor accused the drug companies of "holding us captive to bankrupting the coffers of the State Medicaid drug programs."⁵² One of the critical differences between the Pryor bill and the provision that would be adopted in OBRA 1990 was that the Pryor bill created a barrier to Medicaid coverage for those drugs not subject to discounts, rather than an entrée for drug manufacturers with rebate agreements.⁵³ The only exception under the initial Pryor bill was the requirement that non-discounted drugs be made available if a physician obtained prior approval

Drugs, 1989: Hearings on S. 9058 Before the Senate Comm. on Aging, 101st Cong. 136 (1989) (statement of Sen. Pryor on the rise in prescription drug prices for the elderly). In the speeches marking his retirement from Congress, numerous Senators eulogized this aspect of Pryor's life in Congress. For example, Senator Robert Byrd paid tribute in the following words:

As the Chairman of the Senate Special Committee on Aging for 6 years, Senator PRYOR has led the crusade to protect America's elderly and to oversee Medicare . . . His concern for the elderly has led Senator PRYOR to become an expert on, and a vocal critic of, the prices pharmaceutical companies charge for prescription drugs. And he has matched his criticism with action. Senator PRYOR was instrumental in requiring drug companies to charge the same prices to state-federal Medicaid programs for the poor as they do to other bulk-drug purchasers.

142 CONG. REC. S10,942 (daily ed. Sept. 19, 1996) (statement of Sen. Byrd). Senator Exon similarly described Senator Pryor as:

A leader in keeping pharmaceutical prices low, Senator Pryor has fought long and hard to make sure that Americans do not pay for the low prices pharmaceutical companies charge other countries for their products. Because of his leadership, the Medicaid program instituted a prescription drug rebate program so that drugs could be purchased at a more favorable rate.

142 CONG. REC. S11,265-66 (daily ed. Sept. 25, 1996) (statement of Sen. Exon); *see also* 142 CONG. REC. S11,420-21 (1996) (statement of Sen. Conrad); 142 CONG. REC. S12,300, 12,302 (daily ed. Oct. 3, 1996) (statement of Sen. Lautenberg); 142 CONG. REC. S12,281, 12,283 (daily ed. Oct. 3, 1996) (statement of Sen. Kerry).

⁵¹ S. 3029, 101st Cong. (1990), 142 CONG. REC. S12,954 (daily ed. Sept. 12, 1990) (introduced) (statement of Sen. Pryor). This bill represented a less ambitious version of his earlier effort, S. 2605, the Pharmaceutical Access and Prudent Purchasing Act of 1990. *See* 136 CONG. REC. S5985 (daily ed. May 10, 1990) (statement of Sen. Pryor who introduced the bill).

⁵² 136 CONG. REC. S12,954 (daily ed. Sept. 12, 1990) (statement of Sen. Pryor).

⁵³ *See* Summary of Medicaid Anti-Discriminatory Drug Price and Patient Benefit Restoration Act of 1990, 136 CONG. REC. S12,962 (1990) (statement of Sen. Pryor). "The legislation requires that in order to be placed on a Medicaid prescription drug formulary (the State's covered drug list) - or to be covered by a state Medicaid program, prescription drug manufacturer must provide the Medicaid program the same substantial discounts it is giving to other purchasers of its medications." *Id.*

from the state Medicaid program.⁵⁴ By contrast, the adopted version is affirmative in its coverage—any drug (subject to the exclusions in section 1927) manufactured by a drug company with a rebate agreement must be covered.⁵⁵

The Pryor bill was paralleled in the House by the introduction of H.R. 5589, the Medicaid Prescription Drug Fair Access and Pricing Act of 1990, by Representatives Ron Wyden and Jim Cooper.⁵⁶ As described by Representative Cooper:

[S]ometimes an idea comes along that is so simple, so powerful, and so compelling that people wonder why it hadn't been considered years before. Our colleague in the other body, Senator PRYOR, has come up with such an idea, and my House colleague RON WYDEN, and I, are introducing legislation today in the House to implement that idea.

The idea is simple. When the U.S. Government is a large purchaser of something, it should be able to negotiate to get either the lowest possible price, or at least as good a price as other bulk purchasers are getting⁵⁷

Representative Wyden used even stronger language in explaining his reasons for introducing H.R. 5589, describing the legislation as an effort “to stop the rip-off of the Medicaid pro-

⁵⁴ *See id.*

⁵⁵ In describing his support for this provision of the Omnibus Budget Reconciliation Act of 1990, Senator Orrin Hatch stated as follows:

Although comprising only 40 or so pages of this extremely complex bill, the drug-discount provision has an important and far-reaching impact . . . Of most importance, the Finance Committee plan would provide greater access for Medicaid patients to FDA-approved drugs than would the House version. New drugs would be available immediately to Medicaid patients upon approval by the Food and Drug Administration. These drugs would not be subject to prior approval and would remain fully available for at least 12 months before States could consider placing restrictions on them. Also of utmost importance, the Finance Committee plan, unlike the House version of the legislation, would prohibit the imposition of formularies, [restrictive] lists of drugs. Thus, Medicaid patients would have access to FDA-approved drugs and would not be prohibited from being reimbursed for necessary medicines.

136 CONG. REC. S15,858-59 (daily ed. Oct. 18, 1990) (statement of Sen. Hatch).

⁵⁶ *See* 136 CONG. REC. E2813 (daily ed. Sept. 12, 1990) (statement of Rep. Wyden, Medicaid Deserves Fair Drug Prices).

⁵⁷ 136 CONG. REC. E2826 (daily ed. Sept. 13, 1990) (statement of Rep. Cooper on the Medicaid Prescription Drug Fair Access and Pricing Act of 1990).

gram by pharmaceutical manufacturers.”⁵⁸ Representative Wyden did emphasize that, “[i]n states which use restrictive formularies, beneficiaries will be given new access to a significant number of prescription drugs for which payment had been prohibited.”⁵⁹ The primary goal of both bills, however, was described as an effort “to reduce the approximately \$5 billion in annual State and Federal expenditures for drugs prescribed to Medicaid beneficiaries on an outpatient basis.”⁶⁰

A compromise⁶¹ version of the Pryor-Wyden-Cooper bills was included in section 4401 of the Omnibus Budget Reconciliation Act of 1990.⁶² This legislative change transformed the

⁵⁸ Statement of Rep. Wyden, *supra* note 56, at E2813.

⁵⁹ *Id.* at E2815.

⁶⁰ 138 CONG. REC. S16,134 (daily ed. Oct. 1, 1992) (statement of Sen. Cranston).

⁶¹ Drug manufacturers had proposed their own drug discount plans to undercut the Pryor-Wyden-Cooper proposal. *See* Analysis of Drug Manufacturer Medicaid Drug Discount Proposals and Necessary Elements of Medicaid Drug Price Negotiation Plan (prepared by the Office of Sen. David Pryor), 136 CONG. REC. S12,954, 12,960 (1990).

⁶² *See* 136 CONG. REC. S30,515 (1990) (describing prescription drug discounts and reimbursements). These bills would not be the end of efforts to limit government expenditures for prescription drugs. In 1992, Senator Chafee introduced S2950 to amend title XIX of the Social Security Act “to stop cost shifting by pharmaceutical companies to health care providers by repealing the use of best price and increasing the discount used in determining rebates for prescription drugs purchased under [M]edicaid, to ensure the restoration of prescription drug discounts to various Federal programs, and for other purposes” 138 CONG. REC. S9776 (1992) (statement of Sen. Chafee). A hearing was held before the Subcommittee on Health and the Environment of the House Committee on Energy and Commerce regarding proposals to reform the Medicaid Prescription Drug Rebate Program (HR 2890) and the Medicaid Prescription Drug Amendments Act of 1992 (HR 5614). *See* 138 CONG. REC. D972 (1992) (daily ed. July 31, 1992). Senator Pryor was among the witnesses who testified. *See id.* In considering the Veterans Health Care Act of 1992, Senator Chafee lamented the unintended effect of section 1927 on other purchasers of prescription drugs, especially the Veterans Administration, by increasing costs to these purchasers. *See* 138 CONG. REC. S17,743 (daily ed. Oct. 8, 1992) (statement of Sen. Chafee). In supporting the Veterans Health Care Act of 1992, Senator Rockefeller described section 1927 in the following language:

A little legislative history is appropriate. In 1990, Senator Pryor, my dear friend and colleague, offered the Federal Medicaid Program a means to achieve the discounts that its market share dictates it deserves. As fashioned by Senator Pryor, the Medicaid rebate legislation ensures that the State and Federal Medicaid partnership receives a minimum discount, now 15 percent. That discount is fair compensation to the Federal Government for its status as the single, largest purchaser of pharmaceuticals in the United States. Previously, States had not been successful in obtaining that

treatment of prescription drugs under the Medicaid program.⁶³ Prescription drugs remained an “optional” service that states could elect to include in their state Medicaid plans.⁶⁴ However, once a state chose to cover prescription drugs, subject to the explicit exclusions in section 1927, a state would now be required to cover all medically necessary prescribed drugs produced by manufacturers with rebate agreements in effect.⁶⁵

It is critical to not lose sight of the *quid pro quo* embodied in section 1927 and the significant fiscal savings associated with passage of this provision.⁶⁶ In return for the agreements of

discount in their negotiations with manufacturers, despite the clout that their purchasing power should have commanded.

138 CONG. REC. S17,745 (daily ed. Oct. 8, 1992) (statement of Sen. Rockefeller). Ironically, it was the savings obtained by the Veteran’s Administration through direct negotiation with the drug companies that helped inspire Senator Pryor’s efforts in the first place. See 136 CONG. REC. S5813 (daily ed. May 8, 1990) (statement of Sen. Pryor on the Cost of Prescription Drugs). After the enactment of the reconciliation bill, Senator Jay Rockefeller analogized Senator Pryor to “David” taking on the “Goliath” prescription drug companies with the result that “today we adopted a set of major legislative reforms that will lower the prices of prescriptions drugs sold to the Medicaid Program . . . [by] almost \$2 billion.” 136 CONG. REC. S17,593 (daily ed. Oct. 27, 1990) (statement of Sen. Rockefeller).

⁶³ The opportunities for discounts and rebates were limited prior to the enactment of section 1927. See Alan M. Kirschenbaum & Bruce N. Kuhlík, *Federal and State Laws Affecting Discounts, Rebates, and Other Marketing Practices for Drugs and Devices*, 47 FOOD & DRUG L.J. 533, 540-41 (1992) (discussing Medicare/Medicaid anti-kickback statute and its exemption involving rebates paid by vendors to group purchasing organizations). The Omnibus Budget Reconciliation Act of 1990 also made other changes affecting the pharmaceutical industry. Andrew S. Krulwich, *The Response to Health Care Reform by the Pharmaceutical Industry*, 50 FOOD & DRUG L.J. 1 (1995). Among these changes was the requirement that states adopt rules requiring pharmacists to counsel patients about prescription drug regimens. See 42 U.S.C.A. § 1396r-8(g) (West Supp. 2000); see also Brenda Jones Quick, *The Cost of the Omnibus Budget Reconciliation Act of 1990*, 2 OHIO N.U. J. PHARMACY & L. 145 (1994) (discussing one section of the OBRA of 1990 that puts the duty on each state to pass laws making pharmacists take on legal responsibilities, including counseling patients and obtaining patients’ medical histories).

⁶⁴ Pursuant to section 1902(a)(10)(A) of the Social Security Act (42 U.S.C. §1396a(a)(10)(A) (1994)) and section 1905(a)(12) (42 U.S.C. §1396d(a)(12) (1994)), “prescribed drugs” remain an optional service that may be provided to the categorically and medically needy.

⁶⁵ As described in the House Report, “the Committee bill would require States that elect to offer prescription drugs to cover all of the products of any manufacturer that agrees to provide price rebates.” H.R. REP. NO. 101-881, at 97 (1990), *reprinted in* 1990 U.S.C.C.A.N. 2017, 2109.

⁶⁶ PhRMA, the Pharmaceutical Research and Manufacturers of America, was and is a potent political force. See David S. Hilzenrath, *Drug Firms Rename Lobbying Group: Industry Hopes to Make Itself More Sympathetic During Care Debate*,

manufacturers to limit their charges to state Medicaid programs, states are limited in their discretion in deciding whether to provide reimbursement for specified drugs in their Medicaid plans.⁶⁷ States would benefit from reduced costs for drugs; manufacturers would benefit from an unrestricted formulary.⁶⁸

WASH. POST, May 3, 1994, at D3 (noting the 100 firms the lobby represents); *see also* Brian L. Walser, *Shared Technical Decisionmaking and the Disaggregation of Sovereignty: International Regulatory Policy, Expert Communities, and the Multinational Pharmaceutical Industry*, 72 TUL. L. REV. 1597, 1648 (1998) (remarking upon the "uncommon degree of internal organization among multinational pharmaceutical companies"); Medicaid Anti-Discriminatory Drug Price and Patient Benefit Restoration Act of 1990, 136 CONG. REC. S12,954, 12,954-01 (1990) (statement of Sen. Pryor).

However, this power has been achieved at significant costs as the drug companies learned when they "were told in a confidential report . . . that in the public mind they ranked as low as the tobacco industry . . ." Neil A. Lewis with Robert Pear, *U.S. Drug Industry Fights Reputation for Price Gouging*, N.Y. TIMES, Mar. 7, 1994, at B6. The name of the trade association was changed in order to make it more sympathetic to the public by "emphasiz[ing] drug companies' investment in the development of medicines . . ." Hilzenrath, *supra*. According to Public Citizen's Congress Watch, the drug makers spent more on lobbying in 1999 than any other industry. *See* Nancy McVicar, *Drug Lobbying Irks Consumer Group: \$236 Million Spent to Combat Prescription Plan*, SUN-SENTINEL (Ft. Lauderdale), July 9, 2000, at 11A.

In order to achieve the savings associated with section 1927, savings that would come at the expense of pharmaceutical company profits, there needed to be associated benefits for the drug companies – an opened market for all drugs subject to rebate agreements. The existence of that *quid pro quo* seems to have been ignored by those commentators who have focused on the Medicaid expenses of the *quo* without acknowledging the Medicaid savings from the *quid*.

⁶⁷ As noted by the House Budget Committee:

Under current law, States may, at their option, offer coverage for prescribed drugs. . . . States may limit the number or [sic, of] prescription drugs which they cover through a formulary [sic, formulary]. . . . [T]he Committee bill would require States that elect to offer prescription drugs to cover all of the products of any manufacturer that agrees to provide price rebates.

H.R. REP. NO. 101-881, at 95-97 (1990), *reprinted in* 1990 U.S.C.C.A.N. 2107, 2107-2110.

⁶⁸ Unfortunately, casual readers of the Medicaid statute often miss this distinction. Prescription drugs are "optional" services only in the historical sense that they were not among the original services that states were "required" to provide to the categorically needy. However, since the enactment of section 1927, coverage of prescription drugs subject to rebate agreements has been effectively "required" in state Medicaid plans. One commentator attempted to capture this distinction in the following language: "The federal statute which sets forth the requirements for Medicaid payment of prescription drugs provides that no drug will be covered by any state Medicaid program unless the manufacturer of the drug has entered into an effective 'rebate agreement' with the Secretary of Health and Human Services." Stewart, *supra* note 44, at 616. In fact, a state *could* choose to cover a prescription drug even if the manufacturer did not enter into a rebate agreement, but would not be required to do

Reading these provisions together with the unmodified prior statutory and regulatory requirements⁶⁹ governing prescribed drugs under Medicaid, state Medicaid programs must cover those drugs from manufacturers with rebate agreements so long as the drugs are not otherwise excluded by federal law. However, these drugs may be subjected to limitations on the amount, duration, and scope of coverage,⁷⁰ may be subjected to prior authorization in some cases,⁷¹ and may be subjected to utilization review.⁷²

V. THE CLINTON ADMINISTRATION POSITION

On July 2, 1998, the Health Care Financing Administration⁷³ issued a letter to the states addressing the issue of "Medicaid Coverage of Viagra."⁷⁴ As noted in this letter, "[t]he issue

so. Rather, it would be far more accurate to describe the status of prescription drugs under Medicaid as follows: *The federal statute which sets forth the requirements for Medicaid payment of prescription drugs provides that if a manufacturer of a drug has entered into an effective rebate agreement with the Secretary of Health and Human Services that drug must be covered by every State unless coverage of the drug is otherwise excluded.* This phrasing undercuts any attempt to argue that, pursuant to the *Chevron Doctrine* (announced by the United States in *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984)), the Health Care Financing Administration (HCFA) has exceeded its authority. See Stewart, *supra* note 44, at 619-23 (discussing application of the *Chevron Doctrine* to HCFA regulatory initiatives in this area).

⁶⁹ Final regulations have not yet been issued to implement section 1927. Proposed regulations were issued at 60 Fed. Reg. 48,442 (1995) (to be codified at 40 C.F.R. pts. 441 & 447) (proposed Sept. 19, 1995).

⁷⁰ See 42 C.F.R. § 440.230(c) (1999).

⁷¹ When an item of care or services is subject to prior authorization, a provider (and in some cases a beneficiary) must obtain approval from a review entity within or outside of the state Medicaid agency before reimbursement will be made for the care and services under the state plan.

⁷² When an item of care or services is subject to utilization review, a reviewer or review entity within or outside of the state agency administering the medical assistance program reviews the delivery of care or services to determine the appropriateness of such delivery. Such review is ordinarily conducted after the care or services have been delivered but may occur before payment is made.

⁷³ See Reorganization Order, Dep't of Health, Educ. & Welfare, 42 Fed. Reg. 13,262 (1977).

⁷⁴ See Health Care Financing Admin., *Drug Policy: Medicaid Coverage of Viagra* (last modified July 24, 1998) <<http://www.hcfa.gov/medicaid/drpolicy.htm>>. This directive supplemented the State Medicaid Directors' Drug Rebate Program Release No. 81, issued on July 2, 1998. See also *HCFA Tells States to Pay for Viagra; Pledges to Conduct Rigorous Monitoring*, Health L. Rep. (BNA) at 1096 (July 9, 1998). As indicated by the survey results in Appendix A, rigorous monitoring never occurred.

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).⁷⁵ As HCFA explained, "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."⁷⁶ HCFA then noted that use of Viagra to treat erectile dysfunction in men is not subject to any allowable exclusion or restriction, and that the Secretary had not determined that the drug was subject to clinical abuse or inappropriate use.⁷⁷ Therefore, HCFA concluded that, "the law [section 1927] requires that a State's Medicaid program cover Viagra when medical necessity dictates such coverage for the drug's medically accepted indication."⁷⁸

VI. THE STATE RESPONSE

The reaction to the Clinton Administration pronouncement⁷⁹ was immediate and critical.⁸⁰ On July 2, 1998, the National Governors' Association (NGA),⁸¹ the American Public

⁷⁵ Health Care Financing Admin., *supra* note 74.

⁷⁶ *Id.*

⁷⁷ *See id.*

⁷⁸ *Id.*

⁷⁹ Although some commentators have referred to the HCFA letter as a "directive" that term invests the letter with more official status than it deserves or than it purported to possess. *See Stewart, supra* note 44, at 612. As a form of "interpretive rule," the letter merely explained what was already a requirement by operation of federal statute – section 1927 of the Social Security Act. It could not impose new substantive requirements. *See American Hosp. Ass'n v. Bowen*, 834 F.2d 1037, 1045 (D.C. Cir. 1987).

⁸⁰ *See Robert Pear, New York and Wisconsin Will Defy Federal Directive to Provide Viagra Through Medicaid*, N.Y. TIMES, July 3, 1998, at A12.

⁸¹ The National Governors' Association describes itself as:

[T]he only bipartisan national of, by, and for the nations' Governors. Its members are the Governors of the fifty states, the commonwealths of the Northern Mariana Islands and Puerto Rico, and the territories of American Samoa, Guam, and the Virgin Islands . . . Through NGA, the Governors identify priority issues and deal collectively with issues of public policy and governance at both the national and state levels. The association's mission is to provide a forum for Governors to exchange views and experiences among themselves; assistance in solving state focused problems; information on state innovations and practices; and a bipartisan forum for Governors to establish, influence, and implement policy on national issues.

Welfare Association (APWA),⁸² and the National Association of State Medicaid Directors (NASMD)⁸³ publicly opposed the decision mandating Medicaid coverage of Viagra.⁸⁴

National Governors' Ass'n, *NGA Online: The Organization* (visited July 5, 2000) <<http://www.nga.org/subtocnga.htm>>.

⁸² The American Public Welfare Association is now the American Public Human Services Association (APHSA). The Association describes itself as:

A nonprofit, bipartisan organization of individuals and agencies concerned with human services. Our members include all state and many territorial human service agencies, more than 1,200 local agencies, and several thousand individuals who work in or otherwise have an interest in human service programs. APHSA educates members of Congress, the media, and the broader public on what is happening in the states around welfare, child welfare, health care reform, and other issues involving families and the elderly. The association's mission is to develop, promote, and implement public human service policies that improve the health and well-being of families, children, and adults. APHSA is also an umbrella for several component groups. First among these are the National Council of State Human Service Administrators and the National Council of Local Human Service Administrators. APHSA's affiliate groups include the American Association of Food Stamp Directors, American Association of Public Welfare Attorneys, American Public Human Service Association—Information Systems Management, Association of Administrators of the Interstate Compact on the Placement of Children, National Association for Program Information and Performance Measurement, National Association of Public Child Welfare Administrators, National Association of State TANF Administrators (NASTA), National Association of State Medicaid Directors, National Association of State Child Care Administrators (NASCCA), and the National Staff Development and Training Association.

American Pub. Hum. Serv. Ass'n, *About APHSA* (visited Oct. 11, 2000) <<http://www.aphsa.org/about/about.htm>>.

⁸³ The National Association of State Medicaid Directors (NASMD) describes itself as:

[A] bipartisan, professional, nonprofit organization of representatives of state Medicaid agencies (including the District of Columbia and the territories). Since 1979, NASMD has been affiliated with the American Public Human Services Association (APHSA). The primary purposes of NASMD are to serve as a focal point of communication between the states and the federal government and to provide an information network among the states on issues pertinent to the Medicaid program.

National Ass'n of State Medicaid Dirs., *About NASMD* (visited Oct. 10, 2000) <<http://medicaid.aphsa.org/NASMD.htm>>.

⁸⁴ See National Governors' Ass'n, Press Release, *Viagra Decision Represents Unfunded Mandate: "NGA Opposes Hasty Decision That Increases State Costs and Limits Flexibility"* (July 2, 1998) <<http://www.nga.org/Releases/PR-2July1998Viagra.htm>>; Letter from Linda Wolf, Acting Executive Director, American Pub. Welfare Ass'n, to the Hon. Donna Shalala, Secretary, U.S. Dep't of Health & Hum. Serv., *APWA and NASMD Denounce Decision to Mandate Medicaid Coverage of Viagra*, July 2, 1998 (visited Oct. 14, 2000) <<http://www.apwa.org/hotnews/viagra.htm>>.

In its Press Release, the National Governors' Association "expressed strong opposition to an unfunded mandate."⁸⁵ Of course, independent of the legality or illegality of the action by the Clinton Administration, the mandate is hardly "unfunded." As with other medical assistance services provided pursuant to an approved state plan, the federal government funds between 50 and 83 percent of the costs of care and services.⁸⁶ To be more accurate than, the requirement is better described as a *mostly-funded* mandate.

On the same day that the National Governors' Association issued its press release, the American Public Welfare Association and the National Association of State Medicaid Directors sent a letter to Secretary Shalala expressing concerns about the "recent decision mandating Medicaid coverage of the drug Viagra."⁸⁷ This APWA/NASMD letter described the potential for abuse of the drug and the increasing reports of contraindications.⁸⁸ Based on these factors, the letter expressed disappointment that additional time had not been allowed to gain experi-

⁸⁵ National Governors' Ass'n, *supra* note 84. The issue of "unfunded" mandates remains a major focus for the National Governors' Association. See *Federalism: Hearings on S. 1214 before the Senate Comm. on Governmental Affairs*, 106th Cong. 153-62 (1999) (prepared statement of Governor Michael O. Leavitt, Utah, Vice Chairman, National Governors' Ass'n) (testifying about the problems of federal preemption of state laws and unfunded mandates); see also Donald F. Kettl, *10th Amendment Turf War*, GOVERNING, Oct. 1998, at 13 (outlining the 10th Amendment state/local and federal government's powers debate in light of the decision of the Department of Health and Human Services' ruling that States must make Viagra available to those receiving Medicaid).

⁸⁶ See 42 U.S.C. § 1396b(a)(1) (1994) (describing the computation of the amount of payment to States that have a plan approved under this subchapter as referenced in 42 U.S.C. § 1396d(b) (1994)).

⁸⁷ Letter from Linda Wolf, *supra* note 84.

⁸⁸ Among the concerns associated with the use of Viagra are the cardiac risks associated with sexual activity. As described by Pfizer, "[t]here is a potential for cardiac risk of sexual activity in patients with preexisting cardiovascular disease. Therefore, treatments of erectile dysfunction, including Viagra, should not be generally used in men for whom sexual activity is inadvisable because of their underlying cardiovascular status." See *Viagra.com*, *supra* note 32. These risks were emphasized in the follow-up communication to health professionals reflecting safety information obtained through post-marketing experience. In that communication, Pfizer warned that, "[s]erious cardiovascular events, including myocardial infarction, sudden cardiac death, ventricular arrhythmia, cerebrovascular hemorrhage, transient ischemic attack, and hypertension, have been reported post-marketing in temporal association with the use of VIAGRA. Most, but not all of these patients had preexisting cardiovascular risk factors." *Id.*

ence with the drug before mandating state coverage.⁸⁹ While this language suggested a more reasoned and less hysterical response to the federal action than the NGA communication, the letter went on to again criticize the federal requirement as “an unfunded mandate that is conservatively estimated to cost a minimum of \$100 million per year.”⁹⁰ Several states announced that they would not comply with the HCFA directive.⁹¹

⁸⁹ See Letter from Linda Wolf, *supra* note 84.

⁹⁰ *Id.*; see also National Governors’ Ass’n, *supra* note 84. In another setting, Elaine Ryan, government affairs director for the American Public Welfare Association, was quoted as estimating costs as high as \$200 million attributable to coverage of Viagra. See Amy Goldstein, *U.S. Tells States to Cover Viagra Prescriptions Under Medicaid*, WASH. POST, July 3, 1998, at A21.

Total costs for *all* prescribed drugs and other non-durable medical supplies under the Medicaid program amounted to only \$15.5 billion in calendar year 1998. See Health Care Financing Admin., *National Health Care Expenditures, 1998 National Health Expenditures: Expenditures for Health Services and Supplies Under Public Programs, by Type of Expenditure and Program, Table 10* (visited Oct. 12, 2000) <<http://www.hcfa.gov/stats/nhe%2Doact/tables/t10.htm>>. Moreover, the issue of inflated cost estimates has not been limited to states opposing federally-mandated coverage of Viagra. As described by Dr. Mike Magee, Senior Medical Advisor for Pfizer:

We first got into the public debate on this in California some six or eight weeks ago. Kaiser had made a very public statement that they were not going to cover Viagra because the cost was so extraordinary; that it would lead to people dropping off of insurance rolls and would increase the number of uninsured. As a result, the Commissioner of the Department of Corporations in California called public hearings in San Francisco and Los Angeles. At the public hearings we decided to play a role.

At those public hearings Kaiser stated that this drug would cost their plan \$150 million. The Commissioner asked our reaction to that. Our reaction was that that would be extraordinary consumption indeed, and that Kaiser represents a point or two market share nationwide, and \$150 million is about 25 percent of the total revenue that we will yield for the year in the U.S. from Viagra. It would have been extraordinary consumption on the part of Kaiser men to consume that much Viagra. That was quite clear.

The Commissioner followed up and asked Kaiser what their script experience had been thus far in the first five months. Kaiser said they did not have that data available. The physician president of Blue Shield then stood up in front of the Commissioner and said that Viagra would cost \$36 billion. The Commissioner said that’s an extraordinarily high number. Where did you get that number? He said, it’s quite easy. There are 30 million men in America who have an erectile dysfunction. The product costs \$10 per pill. They’ll use 10 pills per month, and there are 12 months in a year. So, it’s going to cost \$36 billion, and so you should not use this because it’s going to break the bank.

They then asked us what our reaction to that was. My reaction was, it’s true there are 30 million men in the United States who have an erectile dysfunction, but our script experience then at five months allowed us to abso-

Neither the NGA letter nor the APWA/NASMD letters directly challenged the HCFA interpretation of federal law as being inconsistent with the Social Security Act. Instead, these issuances focused on the financial impact on states and on the adverse effect on federal-state relations.⁹²

Both of these communications, therefore, miss the central point. If the Administration reading of section 1927 of the Social Security Act was correct, then the Administration would

lutely predict that only 15 percent of the men would come forward for Viagra In addition to that, we knew that approximately 15 percent of those men who actually did come forward would never get Viagra because they would be on nitroglycerin. It would be contraindicated Another 15 percent would have to be knocked off. On top of that . . . [i]t would only work in approximately 70 percent of the men. So, by the time you started subtracting off, we knew that the rates that were being cited, whether it would be by Medicaid with a hundred million dollar figure or whether it would be by Kaiser or Blue Cross and Blue Shield, were at least tenfold escalated.

Transcript of Pennsylvania Hearing, *supra* note 36, at 14-16. In addition, it is important to recognize that there are offsetting cost reductions associated with covering Viagra. As noted by Dr. Magee:

[E]rectile dysfunction is a marker disease. We know from a variety of different aging studies that if you bring in one million men age 40 to 70 to see the doctor, that in that one million men you will uncover 30,000 cases of untreated diabetes. You'll uncover 50,000 cases of untreated heart disease. You'll uncover 140,000 cases of untreated hypertension. . . . We know that if men will come in with this problem, in the course of a simple history and physical examination, EKG, blood glucose, diseases will be uncovered early in their stage when they are very cost-effectively treated compared to late . . . if you do a cost-benefit analysis on this, you must include the cost savings that would come by having brought these men into the system who otherwise would not come in.

Id. at 17-18. These estimates also ignore the impact on men's lives that may result in such benefits as increased work productivity that may further offset cost estimates. The Medicaid experience from the first quarter attributable to coverage of Viagra showed expenditures under one million dollars. *See id.* at 22. The projections are that the expenditures after full implementation will "come in well under \$10 million; probably closer to \$5 million." *Id.*; *see also Medicaid Viagra Cost Estimates Overstated at Least 10-Fold - Pfizer*, PINK SHEET, Nov. 2, 1998, at 9.

⁹¹ *See Several States Oppose HCFA Order to Pay for Anti-Impotence Drug Viagra*, 7 HEALTH L. REP. (BNA) No. 29, at 1138 (July 16, 1998). Leigh Page, *States Revolt at Covering Viagra Under Medicaid*, AM. MED. NEWS, July 20, 1998, at 1.

⁹² The National Governors' Association also argued that Viagra was still an unproven drug with potentially serious side effects. *See* E-mail from Matt Salo, Senior Health Program Analyst, National Governors' Ass'n, to Leidys Dominguez, Research Assistant (June 10, 1999) (copy on file with author). Some states also expressed concern that Viagra was no more "medically necessary" than drugs that could be excluded under section 1927. *See id.* Of course, that argument does not change the express language of the exclusions in section 1927.

have had no discretion to permit states to exclude Viagra from coverage under approved Medicaid plans. Likewise, if the Administration reading of section 1927 was incorrect, then the Administration would have had no authority to require states to cover Viagra under approved Medicaid plans.

VII. THE ATTEMPT AT A CONGRESSIONAL END-RUN

Critics of the Administration interpretation immediately undertook an effort to preempt the HCFA announcement through recourse to Congress. Through a change in federal law, opponents of Medicaid coverage of Viagra hoped to eliminate any requirement imposed by section 1927.⁹³

H.R. 4274 was the appropriations bill in the 105th Congress for the Departments of Labor, Health and Human Services, and Education, and related agencies for the fiscal year ending September 30, 1999. On July 20, 1998, less than three weeks after the HCFA policy issuance, the House Appropriations Committee reported an appropriations bill covering the Department of Health and Human Services.⁹⁴ Section 218(a) of that bill contained the following language:

LIMITATION ON USE OF FUNDS FOR VIAGRA. —
Except for postsurgical treatment, none of the funds appropriated in this Act shall be expended by the Health Care Financing Administration to reimburse States for Viagra under section 1927 of the Social Security Act.⁹⁵

Section 218(a) thereby would have excluded from Medicaid reimbursement any costs attributable to the provision of Viagra to Medicaid beneficiaries. Section 219 contained the following additional language:

No funds made available in this Act may be used to take any administrative action against States that do not cover Viagra or any other drug or device under section

⁹³ In fact, it was feared that the proposed change in federal law would not only eliminate the requirement, but would actually require states to halt Medicaid funding for the treatment of erectile dysfunction. See Bob Gatty, *States May Be Forced to Half Fund for Impotence Tx*, UROLOGY TIMES (Sept. 1, 1998), at 2.

⁹⁴ See H.R. REP. NO. 105-635 (1998) (Appropriations Bill for Dep't of Labor, Health & Hum. Serv., and Educ., and Related Agencies—to Accompany H.R. 4274).

⁹⁵ H.R. 4274, 105th Cong. § 218(a) (1998).

1927 of the Social Security Act for the treatment of erectile dysfunction.⁹⁶

Section 219 thereby would have insulated any State excluding Medicaid coverage for Viagra from any compliance proceeding on the grounds that the state plan did not comply with governing federal law.⁹⁷

Sections 218(a) and 219 of H.R. 4274 did not become law, however, as the Conference Committee rejected the House provision.⁹⁸ On November 30, 1998, with its interpretation of fed-

⁹⁶ H.R. 4274, 105th Cong. § 219 (1998).

⁹⁷ Pursuant to section 1904 of the Social Security Act, state plans are subject to a compliance proceeding process as follows:

Operation of State plans.

If the Secretary, after reasonable notice and opportunity for hearing to the State agency administering or supervising the administration of the State plan approved under this subchapter, finds-

- (1) that the plan has been so changed that it no longer complies with the provisions of section 1396a of this title; or
- (2) that in the administration of the plan there is a failure to comply substantially with any such provision;

the Secretary shall notify such State agency that further payments will not be made to the State (or, in his discretion, that payments will be limited to categories under or parts of the State plan not affected by such failure), until the Secretary is satisfied that there will no longer be any such failure to comply. Until he is so satisfied he shall make no further payments to such State (or shall limit payments to categories under or parts of the State plan not affected by such failure).

42 U.S.C. § 1396(c) (1994). The range of options available to the Health Care Financing Administration to bring states into compliance with federal law also includes other mechanisms for withholding federal funds. See Eleanor D. Kinney, *Rule and Policy Making for the Medicaid Program: A Challenge to Federalism*, 51 OHIO ST. L.J. 855, 863-64 (1990) (detailing options such as compliance actions, disallowance actions, and the quality control system).

Some legislators did not wait for the legislative process to be completed. Representative David McIntosh, Chairman of the Regulatory Subcommittee of the House Government Reform and Oversight Committee, pronounced, in a letter to all 50 governors, that the HHS directive "has no legal force or effect and should not be regarded as binding on the states." *States Told to Ignore Viagra Directive*, SUNDAY ADVOCATE (Baton Rouge, La.), Aug. 9, 1998, at 12-A (quoting Rep. David McIntosh, R-Ind.). Of course, the HHS directive was never intended to have the legal force or effect of law. See *id.* Rather, all it purported to do was remind states of the existing requirements of federal law – section 1927 of the Social Security Act.

⁹⁸ The Conference Report provided as follows:

Medicaid Funding for Viagra.

The conference agreement does not include sections 218 and 219 of the House bill. The Senate bill contained no similar provisions. There are concerns about clinical and financial abuse of these drugs that could endanger the health of patients and undermine the public support for the Medicaid

eral law undisturbed by Congress, HCFA again reminded the states that they must cover Viagra.⁹⁹

Meanwhile, States quickly divided into three camps. Most immediately added coverage of Viagra to their Medicaid programs.¹⁰⁰ A few "weighed" the mandate and their response to the HCFA directive before adding coverage of Viagra.¹⁰¹ Others chose to exclude Viagra from coverage.¹⁰² We must therefore

program that often cannot adequately provide basic health care for all needy individuals. Therefore, HCFA is encouraged to establish a rigorous system to review utilization of these drugs by working with States, clinicians, consumer advocates, and others to assure consistent collection of data necessary to make the exclusion determination under section 1927(d)(3) if the drug is subject to clinical abuse or inappropriate use.

H.R. REP. NO. 105-825, at 1294 (1998) (Report entitled *Making Omnibus Consolidated and Emergency Supplemental Appropriations for Fiscal Year 1999: Conference Report to Accompany H.R. 4328*).

⁹⁹ See Letter from Sally K. Richardson, Director, Center for Medicaid & State Operations, Health Care Financing Admin. (HCFA), to State Medicaid Directors (Nov. 30, 1998) (reprinted at <<http://www.hcfa.gov/medicaid/smd11308.htm>> (on file with the author)).

¹⁰⁰ Section 1927 requires coverage of all approved drugs manufactured by drug companies that have rebate agreements in effect. There is no waiting period in the statute. Despite this fact, Medicaid coverage of Viagra was not automatic in many states. For example, New York argued that, "[i]t is the State's right to review specific drugs for any time necessary to determine whether or not there are state issues pertaining to the coverage of a drug." E-mail from Mark Butt, Director of Pharmacy Policy & Operations, Bureau of Program Guidance, Office of Medicaid Management, N.Y. State Dep't of Health, to Leidys Dominguez, Research Assistant (June 23, 1999) (on file with author).

¹⁰¹ See generally *Medicaid-Prescription Drugs: Several States Oppose HCFA Order to Pay for Anti-Impotence Drug Viagra*, 7 Health Law Rep. (BNA) 1138, 1138-39 (July 16, 1998) (describing how states have struggled with the issue of including Viagra in their Medicaid program). South Carolina and Michigan fell into this camp. In Pennsylvania, a hearing, "Access to Pharmaceutical Services in the Medical Assistance Program," was held on October 8, 1998 before the Health and Human Services Committee of the Pennsylvania House of Representatives. See Transcript of Pennsylvania Hearing, *supra* note 36 (describing the apparent need for Pennsylvania to convene a special committee among the House to "weigh" these issues).

¹⁰² New York and Oregon fell into this camp. Matt Salo, Senior Health Policy Analyst for the National Governors' Ass'n, stated that these states that are not covering the drug at all "are not doing so in a blatant attempt to flaunt HCFA authority," but instead because they are "truly concerned about the social and fiscal implications of covering the drug." E-mail from Matt Salo, *supra* note 92.

Oregon is an especially complicated state to analyze because it operates its Medicaid program pursuant to a broad waiver of many federal requirements. See 4 Medicare & Medicaid Guide (CCH) ¶ 15,630 (introducing Oregon's Medicaid program as a § 1115 demonstration project waiver known as the Oregon Health Plan).

resolve the question of whether the Administration interpretation of federal law is correct since Medicaid plan compliance is at stake in the states deviating from the HCFA directive.¹⁰³

VIII. THE IRONY OF THE DISPUTE

It is ironic that the first major dispute about the application of section 1927 has arisen in the context of a medication tar-

This program expands eligibility to poverty level individuals (133% of poverty level for pregnant women, infants and children under age six). Services are delivered by fully and partially capitated plans and primary care case management programs. A public prioritization process is used to establish the service package provided under the Oregon Health Plan. Implementation of this waiver was February 1, 1994 . . .

Id.; see also John Kitzhaber & Mark Gibson, *The Crisis in Health Care-The Oregon Health Plan as a Strategy for Change*, 3 STAN. L. & POL'Y REV. 64 (1991) (discussing whether the Oregon plan is a reasonable step in moving from a failing system to one that works). See generally James V. Garvey, Note, *Health Care Rationing and the Americans with Disabilities Act of 1990: What Protection Should the Disabled Be Afforded*, 68 NOTRE DAME L. REV. 581, 586 (1993) (listing the primary principles behind the Oregon plan); Greg P. Roggin, *The "Oregon Plan" and the ADA: Toward Reconciliation*, 45 WASH. U. J. URB. & CONTEMP. L. 219 (1994) (describing the history and current status of the Oregon Basic Health Services Act).

The State currently offers treatment for 574 conditions out of a list of 743 compiled by Oregon Health Plan officials. See Oz Hopkins Koglin, *State Health Officials Urged to Restore Viagra Coverage*, THE OREGONIAN, Aug. 27, 1998, at D9. Impotence caused by organic problems ranks number 542 on the list of 574 funded items and is therefore covered for treatment with Viagra. By contrast, impotence caused by inorganic sources, such as mental disorders, ranks number 578, and treatment is therefore not covered. See *Insurers Develop Strict Rules on Coverage for Impotence Pills*, THE OREGONIAN, Apr. 29, 1998, at A1, A16; *Viagra Coverage: Oregon Says 'Yes,' But Not Alabama*, AM. HEALTH LINE, May 8, 1998. By the fall of 1998, that situation had changed and Oregon terminated its coverage of Viagra. This was accomplished by reclassifying all treatment with Viagra from organic disorders on line 544 to sexual dysfunction of psychological origin on line 578. See Hopkins Koglin, *supra*.

Effective June 1, 1999, the New York Medicaid agency announced that it would cover Viagra under its State Medicaid program. See Letter from Gregor N. Macmillan, Director of Provider Relations, Office of Medicaid Management, Department of Health, State of New York to New York pharmacists (June 3, 1999) (on file with author); see also New York Dep't of Health, *Attention Medical Prescribers and Pharmacy Providers*, DOH MEDICAID UPDATE, June 1999 (visited Oct. 12, 2000) <<http://www.health.state.ny.us/nysdoh/manicare/omm/0699med.htm>>. New York decided to add Medicaid coverage of Viagra after legislative efforts to expand the authority of the Secretary of Health and Human Services to exclude drugs like Viagra from Medicaid coverage or to expand the authority of the states to exclude certain drugs from coverage. See E-mail from Mark Butt, *supra* note 100.

¹⁰³ See 42 U.S.C. § 1396(c) (1994) (explaining State compliance plan).

geted at men, usually of advanced years.¹⁰⁴ Because of the eligibility requirements of the Medicaid program, the vast majority of Medicaid beneficiaries are children and female caretaker relatives.¹⁰⁵ Although elderly and disabled beneficiaries do utilize the majority of services under State Medicaid programs, primarily for coverage of long-term care, it is not clear that people in nursing homes and chronic care hospitals really are the target population for Viagra.

It is also ironic that it was the Clinton Administration that chose to create a confrontation with the states over this issue. As Governor of Arkansas, Bill Clinton was one of the three drafters of a resolution for the National Governors Association opposing the enactment of any new Medicaid mandates by Congress.¹⁰⁶ That resolution was supported by nearly every governor.¹⁰⁷ The Congressional amendments, adamantly op-

¹⁰⁴ Research on the use of Viagra in women has been less promising. See Steven A. Kaplan et al., *Safety and Efficacy of Sildenafil in Postmenopausal Women with Sexual Dysfunction*, 53 *UROLOGY* 481 (1999) (concluding that, while sildenafil was well tolerated in postmenopausal women with sexual dysfunction, overall sexual function did not improve significantly).

¹⁰⁵ HCFA has emphasized that since "only about 10 percent of Medicaid beneficiaries are adult males," the number of patients who could be diagnosed with erectile dysfunction is rather small. *Prescription Drugs: HCFA Tells States to Pay for Viagra; Pledges to Conduct Rigorous Monitoring*, 7 *Health Law Rep. (BNA)* 1096, 1097 (July 9, 1998). There appears to be a small, but potentially important, role that Viagra (sildenafil) can play for certain women. See H. George Nurnberg, et al., *Sildenafil for Women Patients with Antidepressant-Induced Sexual Dysfunction*, 50 *PSYCHIATRIC SERVICES* 1076 (1999).

¹⁰⁶ The other drafters were then-Governor Richard Celeste of Ohio, then Chairman of NGA's Committee on Human Resources, and then-Governor Garrey Carruthers of New Mexico. See Julie Rovner, *Governors' Medicaid Protests Likely to Be Swept Aside*, 47 *CONG. Q. WKLY. REP.* 2121, 2122 (1989). Clinton's role became the focus of an effort by the Children's Defense Fund, an organization that was then chaired by Hillary Clinton, to expose Clinton's perceived hypocrisy in opposing legislation that was an outgrowth of efforts by the Southern Regional Project on Infant Mortality, a task force led by former Governor Richard W. Riley of South Carolina, and that was consistent with positions espoused by Clinton in many public speeches. See *id.* at 2121; see also Maria Henson, *Children's Fund Criticizes Clinton on Medicaid Issue: Governors Association Letter Assailed*, *ARK. GAZETTE*, Aug. 19, 1989, at 10B.

¹⁰⁷ The only governor who refused to sign the resolution was Mario M. Cuomo of New York. See Letter from National Governors' Ass'n to Members of Congress (Aug. 1, 1989) (on file with author). As explained by Brad C. Johnson, head of New York State's Washington D.C. office:

We are not opposed to expansion of Medicaid to poor pregnant women, infants and children and that's why we did not sign the letter . . . Congress is

posed by the governors, were ultimately enacted to expand Medicaid eligibility and services for low-income children and pregnant women.¹⁰⁸

The Clinton Administration has also taken the lead in granting waivers of provisions of the Medicaid statute,¹⁰⁹ in-

on the right track, and as long as they're willing to pay part of the freight, we're willing to go along.

Rovner, *supra* note 106, at 2122. Then-Governor Buddy Roemer of Louisiana also failed to sign the resolution. However, he spoke in favor of the resolution at the NGA meeting, but could not be located before the letter was sent. *Id.*

¹⁰⁸ The bipartisan proposal was initially proposed by President Bush in his Fiscal Year 1990 budget. *See* Rovner, *supra* note 106, at 2121. That proposal would have required "states to cover infants and pregnant women in families with incomes up to 130 percent of the poverty level." *Id.* The House Energy and Commerce Committee and Senate Finance Committee bills would have required "states to extend Medicaid coverage to pregnant women and to infants up to age 1 in families with incomes below 185 percent of the federal poverty [line]." *Id.* As finally enacted, the legislation achieved several goals. First, it mandated eligibility for low-income pregnant women and infants with family incomes up to 133 percent of the federal poverty line. *See* 42 U.S.C.A. § 1396a(l) (West Supp. 2000); Omnibus Budget Reconciliation Act of 1990, Pub. L. No. 101-508, § 4601, 104 Stat 1388, 1388-166. Second, it permitted states to expand eligibility for low-income pregnant women and infants with family incomes between 133 and 185 percent of the poverty line. *See* 42 U.S.C.A. § 1396a(e) (West Supp. 2000). Third, it requires states to ultimately cover all children with family incomes below 100 percent of the poverty line. *See* 42 U.S.C.A. § 1396a(l)(2)(C) (West Supp. 2000). Fourth, it required states to cover all medically necessary care required by a Medicaid-eligible child under the early and periodic screening, diagnosis, and treatment (EPSDT) program, even if such services were not covered for adults. *See* 42 U.S.C.A. § 1396a(a)(43) (West Supp. 2000). Fifth, it required states to provide all services required by pregnant women for treatment of conditions that "might complicate pregnancy." *See* 42 U.S.C.A. § 1396a(a)(10)(G) (West Supp. 2000).

Repeal of these requirements continued to be a priority of the states. *See* NATIONAL GOVERNORS' ASSOCIATION, POLICY POSITIONS: FEBRUARY 1998, Policy EC-8.3.4 (effective Winter meeting 1997 to Winter meeting 1999) (copy on file with author). "Under current policy, states have no ability to limit the range or cost of services required in the EPSDT program. This open-ended requirement is driving up the cost of the Medicaid budget at uncontrollable rates." *Id.*; *see also* National Conference of State Legislatures, *Health: Goals for State Federal Action* (July 1998) (copy on file with author). "Under current law, states are required to provide EPSDT to children in the Medicaid program. States are required to treat any condition diagnosed during the screening, even if the procedure or service is not covered under the state's Medicaid plan. This compromises the ability of the states to limit the range or costs of Medicaid services." *Id.*

¹⁰⁹ Section 1115 of the Social Security Act (42 U.S.C. § 1315 (1994)) authorizes the Secretary of Health and Human Services to waive requirements of federal law in order to permit states to engage in experimental projects that are likely to assist in promoting the objectives of the Medicaid program. *See* Vernellia Randall et al., *Section 1115 Medicaid Waivers: Critiquing the State Applications*, 26 SETON HALL L. REV. 1069 (1996). "Congress intended to permit projects that would help

cluding waivers that were denied by other administrations.¹¹⁰ It is, at best, conjecture to suggest that the reason that the Clinton Administration singled out prescribed drugs for a well-publicized confrontation with the states related to the role played by Vernon Jordan in working on this legislation as a lobbyist for the pharmaceutical manufacturers.¹¹¹

However, despite claims of fiscal catastrophe, it does seem clear that if this drug did not involve sexual expression, it would not have been singled out for exclusionary treatment by state Medicaid agencies.¹¹² It is revealing that, in covering this

improve the programs for beneficiaries ... A basic premise of the waiver is the ability of states to assure cost neutrality for the federal government, reduce health care costs for the state, and increase services without reducing quality. State waivers have often been developed as a part of a larger state insurance reform." *Id.* at 1074-75.

¹¹⁰ See Medicare & Medicaid Guide (CCH), *supra* note 102; see also Kitzhaber & Gibson, *supra* note 102. See generally Garvey, *supra* note 102, at 586; Roggin, *supra* note 102.

¹¹¹ Vernon Jordan became one of the most powerful persons in Washington during the Clinton Administration after chairing the Clinton Transition Team. See Mark Fisher, *First Friend: Vernon Jordan is a Man Comfortable with Power. And With Himself*, WASH. POST, Jan. 27, 1998, at E1. After a decade as Executive Director of the National Urban League, Jordan became a partner at Akin, Gump, Strauss, Hauer & Feld, where he lobbied on behalf of drug companies and other clients. See Dan Balz, *Weight of Clinton's Problems Tests Strength of Advisers' Loyalty*, WASH. POST, Feb. 22, 1998, at A20. This was true despite the absence of Jordan's name on lobbying reports required under the Lobbying Disclosure Act of 1995. See J. Gregory Sidak, Review Essay, *The Petty Larceny of the Police Power*, 86 CAL. L. REV. 655, 665 (1998) (reviewing FRED S. MCCHESENEY, MONEY FOR NOTHING: POLITICIANS, RENT EXTRACTION, AND POLITICAL EXTORTION (1997)).

As discussed *supra* notes 45-72 and accompanying text, section 1927 had its roots in legislation proposed by Senator David Pryor of Arkansas. See *Lobbying Disclosure Conference Report*, 140 CONG. REC. S13,945, 13,949 (daily ed. Oct. 3, 1994) (statement of Sen. Levin). In 1990, Pryor suggested that "the Medicaid program could save \$300 million a year by adopting the same discount drug-buying strategies used at a number of hospitals and national health maintenance organizations." Christopher Drew & Michael Tackett, *More and More, Lobbyists Call Shots in D.C.*, CHI. TRIB., Dec. 6, 1992, at 1. The drug lobby hired Vernon Jordan to help recruit black and Hispanic groups willing to denounce the idea. See *id.* As described in the article, "[t]he leaders of one black organization then sent out their own letters claiming that [Senator] Pryor's plan [to reduce reimbursement to drug manufacturers] represented the kind of approach used whenever 'mean-spirited bigots want to strike at the black underclass.'" *Id.* at 15. A spokesman for the Pharmaceutical Manufacturers Association (now the Pharmaceutical Research and Manufacturers Association, PhARMA) was quoted as denying that the group was "exploiting any racial aspect" of the issue. *Id.*

¹¹² The resistance of health insurers to covering matters of sexual and reproductive health is not limited to government health insurance programs. See Hazel

issue, the Associated Press wire story described the issue in the following terms: "The blue, diamond-shaped potency pill from Pfizer, Inc. has forced several states to weigh the importance of sex against other pressing public policy concerns that require funding."¹¹³ The use of loaded language to frame the issues was evident in the differing use that newspapers made of the Associated Press story.¹¹⁴ Editorials also emphasized that if poor people wanted to have fun, they should stop being poor.¹¹⁵ This attitude was exacerbated by the queasiness with which many people approach the topic of sex and the elderly or disabled.¹¹⁶

IX. SECTION 1927 AND COVERAGE OF VIAGRA

It is against this legal, political, and social backdrop that the current dispute over Medicaid coverage of Viagra must be analyzed.¹¹⁷ If States have discretion to not include prescribed

Glenn Beh, *Sex, Sexual Pleasure, and Reproduction: Health Insurers Don't Want You to Do Those Nasty Things*, 13 WIS. WOMEN'S L.J. 119 (1998).

¹¹³ John Hendren, *10 States Paying for Viagra for Poor*, DAYTON DAILY NEWS, May 8, 1998, at 5A; see also John Hendren, *States Differ Over Extent Medicaid Should Provide New Impotence Pill*, BUFFALO NEWS, May 8, 1998, at 14A.

¹¹⁴ Compare John Hendren, *Medicaid Viagra Coverage Not Available in Some States: Insurers are Denying, Limiting Benefits for Impotence Treatment*, SEATTLE TIMES, May 9, 1998, at A3 ("While Alabama and Florida allow the impoverished impotent four *Viagra* pills per month . . .") (emphasis added) with *Yep, Florida's One of 10 States Giving Viagra to Impotent Poor*, PRESS J., May 8, 1998, at D1 ("While Alabama and Florida allow the impoverished impotent four *state-funded liaisons* a month . . .") (emphasis added).

¹¹⁵ See Editorial, *Free Love? States Shouldn't Have to Pay for Viagra*, COLUMBUS DISPATCH, Aug. 29, 1998, at A14 (criticizing the federal mandate of "free whoopee at taxpayers' expense").

¹¹⁶ One of the few voices to the contrary was provided by Joe Gelarden, *Much Ado Over \$10 Pill*, INDIANAPOLIS NEWS, Oct. 16, 1998, at C1. "Maybe [the furor] is because the baby boomers and blonds under 35 think intimacy is only for the young, flat-tummied, firm-breasted, strong-armed, thick-haired folks who turn up their noses at the idea of sex after 40, or 50, or 60, or older." *Id.* Another rational voice was provided by Elizabeth S. Lawton, Commissioner of the Bureau for Medical Services of the West Virginia Department of Health and Human Resources. See Elizabeth S. Lawton, *Medicaid Has to Pay for Viagra; Congress Limits What States May Refuse to Provide*, CHARLESTON DAILY MAIL, May 28, 1998, at 4A. "While it may seem appropriate to some to challenge Medicaid's limited coverage of the impotence drug Viagra, such an argument is based on several fallacies and faulty presumptions and serves no purpose but to perpetuate the negative perception of West Virginia's Medicaid program held by those unfamiliar with the complexities of the Medicaid system and the external forces that drive it." *Id.*

¹¹⁷ This is admittedly not the only dispute involving Viagra. Some have argued that providing insurance coverage of Viagra, a "male" drug, while coverage of female oral contraceptives is excluded, constitutes sex discrimination. See *ACOG*

drugs at all in their State plans, why could they not choose to exclude Viagra from coverage? If States have wide discretion to limit the amount, duration, and scope of required and optional services, why could they not choose to exclude Viagra from coverage or to greatly limit its availability to Medicaid beneficiaries?

There are, therefore, two parts to any inquiry regarding Medicaid coverage of a care or service. First, is the care or service generally reimbursable in the state plan? Second, if the care or service is generally reimbursable, is it reimbursable for this particular beneficiary under these particular circumstances? The answer to the first question is rather easy with regard to Viagra; the second question is far more complicated to answer.

Pfizer, Inc., the manufacturer of Viagra, has executed a rebate agreement with the federal government that covers Viagra.¹¹⁸ Since it has a rebate agreement in effect that covers state Medicaid programs,¹¹⁹ section 1927 is triggered and

Exposes Gender Bias of Viagra Coverage, FEMINIST NEWS (Feminist Majority Foundation) (May 12, 1998) <<http://www.feminist.org/news/newsbyte/may98/0512.htm>> (reporting the view of the American College of Obstetricians and Gynecologists); see also *Equity in Prescription and Contraception Coverage Act*, 144 CONG. REC. S4772 (daily ed. May 13, 1998) (statement of Senator Reid); Kathleen O'Connor and Margaret Heldring, *Viagra and Contraceptives: Gender Equity*, SEATTLE TIMES, July 20, 1998, at B5. However, these arguments are inapplicable to the issue of Medicaid coverage of Viagra since oral contraceptives and other family planning supplies are a required service in all state Medicaid plans. See 42 U.S.C.A. § 1396d(a)(4)(C) (West Supp. 2000) (providing in the definition of medical assistance "family planning services and supplies (directly or under arrangements with others) to individuals of child-bearing . . . age who are eligible under the State plan"); see also Diane Lore, *Insurers Slow to See Benefits of the Pill*, ATLANTA J., May 9, 2000, at C1 (describing Georgia state law requiring insurance plans to cover the cost of contraceptives if they cover other prescriptions such as Viagra). Others have questioned the "medicalization" of sexuality and the impact of health care provider and drug company profits, especially on female sexual dysfunction. See Meika Loe, *Female Sexual Dysfunction: For Women or for Sale?*, NETWORK NEWS (National Women's Health Network, Wash., D.C.), Jan.-Feb. 2000, at 1, 6.

¹¹⁸ Telephone interview by Sandra Lee with Jim Roper, Government Contracts, Pfizer, Inc. (Oct. 20, 1999) (notes from telephone interview on file with author); Telephone interview by Sandra Lee with Dennis Tolbert, National Accounts for Contracting, Pfizer, Inc. (Oct. 20, 1999) (notes from telephone interview on file with author). Because the rebate agreement contains proprietary information, Pfizer representatives declined to make a copy of the actual rebate agreement available. The confidentiality of these rebate agreements is protected under section 1927(b)(3)(D) of the Social Security Act. See 42 U.S.C.A. § 1396r-8(b)(3)(D) (West Supp. 2000).

¹¹⁹ A copy of the form rebate agreement between the Secretary of Health and Human Services and pharmaceutical manufacturers is on file with the author. This

Viagra must be included in State Medicaid plans.¹²⁰ However, inclusion of a drug in a State Medicaid formulary is not the same as making that drug available to all patients, at all times, under all circumstances. Access to Viagra may then potentially be controlled through three techniques: (1) limits on amount, duration, and scope of services imposed before Viagra is prescribed; (2) prior authorization requirements as Viagra is prescribed for a particular Medicaid beneficiary; and (3) utilization review of treatment decisions to prescribe Viagra to a particular Medicaid beneficiary after it is dispensed.

A. Limits on Amount, Duration, and Scope

Since the inception of the Medicaid program in 1965, states have been authorized by federal law to impose limits on the amount, duration, and scope of services provided to Medicaid beneficiaries.¹²¹ The "amount, duration, and scope" requirement

form agreement was initially proposed as Medicaid: Prescription Drug Rebate Agreement. *See* Medicaid Program; Drug Rebate Agreement, 56 Fed. Reg. 7049, 7050-54 (1991).

¹²⁰ None of the exclusions in section 1927 is applicable to Viagra. Viagra is not an agent used for anorexia, weight loss, or weight gain; an agent used for cosmetic purposes or hair growth; an agent used for the symptomatic relief of cough and colds; an agent used to promote smoking cessation; a prescription vitamin and mineral product; a nonprescription drug; a covered outpatient drug 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; a barbiturate; or a benzodiazepine. *See* 42 U.S.C.A. § 1396r-8(d)(2) (West Supp. 2000) (listing the classes of drugs subject to restriction). The only exclusion that some have argued is applicable is the exception for "agents when used to promote fertility." 42 U.S.C.A. § 1396r-8(d)(2)(B) (West Supp. 2000); *see also Medicaid Coverage of Viagra*, AFI HEALTH COMMITTEE REP. (National Conference of State Legislatures, Wash., D.C.) July 1998, at 1. This argument was, of course, rejected by HCFA.

¹²¹ *See* 42 C.F.R. § 440.230 (1999), *supra* note 43. This section was promulgated in 1981 after the split of the Department of Health, Education, and Welfare into the Departments of Education and Health and Human Services in 1979. *See* Medicaid Eligibility and Coverage Criteria, 46 Fed. Reg. 47,993 (1981) (The Department of Health, Education, and Welfare was redesignated as the Department of Health and Human Services by Pub. L. No. 96-88, tit. V, § 509, 93 Stat. 695 (1979)). However, the language essentially repeated the regulatory requirements in place from 1966 to 1981. *See* 42 C.F.R. § 440.230 (1979); 45 C.F.R. § 249.10 (1974).

Although this section is based on the authority of section 1102 of the Social Security Act (42 U.S.C. § 1302), it implements 42 U.S.C. § 1396a(a)(10) (1994):

A state plan for medical assistance shall provide . . .

(B) that the medical assistance made available to any individual described in subparagraph (A) [the categorically needy] –

(i) shall not be less in amount, duration, or scope than the medical assistance made available to any other such individual, and

has been the subject of substantial litigation since 1965.¹²² Although the United States Supreme Court has interpreted certain aspects of the "amount, duration, and scope" requirement,¹²³ it has never ruled on the level of medical care and services that is

(ii) shall not be less in amount, duration, or scope than the medical assistance made available to individuals not described in subparagraph (A);

(C) that if medical assistance is included for any group of individuals described in section 1396d(a) [section 1905 of the Social Security Act] who are not described in subparagraph (A) or (E), then –

(i) the plan must include a description of (I) the criteria for determining eligibility of individuals in the group for such medical assistance, (II) the amount, duration, and scope of medical assistance made available to individuals in the group

42 U.S.C. § 1396a(a)(10)(B), (C) (1994).

¹²² The first major case upholding limits on the amount, duration, and scope of Medicaid services was *District of Columbia Podiatry Soc'y v. District of Columbia*, 407 F. Supp. 1259 (D.C. 1975). This was followed in rapid succession by *Virginia Hosp. Ass'n v. Kenley*, 427 F. Supp. 781 (E.D. Va. 1977) (upholding Virginia's 21-day limit on coverage of inpatient hospital services); *Dodson v. Parham*, 427 F. Supp. 97 (N.D. Ga. 1977) (invalidating Georgia's restrictive prescription drug formulary); *Beal v. Doe*, 432 U.S. 438 (1977) (upholding Pennsylvania's exclusion of coverage of abortion services that were not medically necessary); *Curtis v. Taylor*, 625 F.2d 645 (5th Cir. 1980) (upholding Florida's limitation of coverage of physician's services to three visits per month); *Charleston Mem'l Hosp. v. Conrad*, 693 F.2d 324 (4th Cir. 1982) (upholding South Carolina's 12 days per year limitation on inpatient hospital services and 18 visits per year limitation on outpatient services); *Meyers v. Reagen*, 776 F.2d 241 (8th Cir. 1985) (invalidating Iowa's exclusion of electronic speech devices from coverage); *Ledet v. Fischer*, 638 F. Supp. 1288 (M.D. La. 1986) (invalidating Louisiana's limitation on coverage of eyeglasses to post-cataract surgery patients); *Cowan v. Myers*, 232 Cal. Rptr. 299 (Ct. App. 1986) (upholding California's limitation on "medically necessary" services to those "reasonably necessary to protect life, to prevent significant disability or illness, or to alleviate severe pain"); *Weaver v. Reagen*, 886 F.2d 194 (8th Cir. 1989) (invalidating Missouri's exclusion of azidothymidine to treat certain diagnoses or conditions); *Visser v. Taylor*, 756 F. Supp. 501, 506 (D. Kan. 1990) (invalidating the Kansas exclusion of Clozaril from Medicaid coverage); *Sobky v. Smoley*, 855 F. Supp. 1123 (E.D. Cal. 1994) (enjoining California to provide sufficient methadone treatment services); *Hope Med. Group for Women v. Edwards*, 63 F.3d 418 (5th Cir. 1995) (invalidating Louisiana's exclusion of certain medically necessary abortions); *Hern v. Beye*, 57 F.3d 906 (10th Cir. 1995) (invalidating Colorado's exclusion of certain abortions resulting from rape or incest); *Kirk v. Dunning*, 370 N.W.2d 113 (Neb. 1985) (invalidating Nebraska's exclusion of periodontal services); *DeSario v. Thomas*, 139 F.3d 80 (2nd Cir. 1998) (upholding Connecticut's limits on coverage of durable medical equipment); and *Smith v. Palmer*, 24 F. Supp. 2d 955 (N.D. Iowa 1998) (invalidating Iowa's exclusion of sex reassignment surgery).

¹²³ These interpretations have occurred mostly in the context of restrictions on Medicaid funding for abortion services. See *Beal v. Doe*, 432 U.S. 438 (1977) (upholding refusal by the Commonwealth of Pennsylvania to pay for non-therapeutic abortions under the State's medical assistance program).

necessary to satisfy this requirement.¹²⁴ In the meantime, we are left with a conflict between the circuits as to the extent to which states are required to cover all medically necessary care and services when that care or service is included in the State Medicaid plan.¹²⁵ At a minimum, States are required to provide an item of care or service in sufficient amount, duration, and scope to meet the needs of most recipients.¹²⁶ At most, States are re-

¹²⁴ In *Alexander v. Choate*, 469 U.S. 287 (1985), the Supreme Court upheld a Tennessee reduction on Medicaid coverage of inpatient hospital days from 20 to 14 days per fiscal year against a challenge under section 504 of the Rehabilitation Act of 1973 (29 U.S.C. § 794). The Supreme Court observed that the District Court had found that "the 14-day limitation would fully serve 95% of even handicapped individuals eligible for Tennessee Medicaid . . ." *Id.* at 303. Although that language sounds like the standard used in such cases as *Curtis v. Taylor* and *Virginia Hospital Association v. Kenley*, the Supreme Court went on to declare, "[b]ecause that conclusion is unchallenged, we express no opinion on whether annual limits on hospital care are in fact consistent with the Medicaid Act." *Id.* at 303 n.23.

¹²⁵ This conflict is highlighted by the decisions of the Court of Appeals for the Eighth Circuit in *Weaver v. Reagen*, 886 F.2d 194 (8th Cir. 1989) and of the Court of Appeals for the Fifth Circuit in *Curtis v. Taylor*, 625 F.2d 645 (5th Cir. 1980). In *Weaver*, the Court of Appeals held that the State of Missouri could not deny Medicaid coverage of AZT for AIDS patients whose doctors determined that administration of the drug was medically necessary. By contrast, in *Curtis*, the Court of Appeals held that Florida could deny medically necessary physician care to patients who required more than three doctor visits per month.

¹²⁶ This standard was probably first clearly enunciated in *Virginia Hosp. Ass'n v. Kenley*, 427 F. Supp. 781 (E.D. Va. 1977). In this case, the district court upheld a Virginia Medicaid regulation limiting coverage of inpatient hospital services to 21 days. *See id.* at 784. The trial court acknowledged that such a limit would result in the denial of medically necessary care for at least some recipients. *See id.* at 785 (conceding that "[u]nquestionably, there are Medicaid recipients in Virginia who require, as a matter of medical necessity, more than 21 days of hospitalization").

In *Kenley*, Judge Merhige noted that the decision came down to the proper construction of the federal "amount, duration, and scope" regulation (then found at 45 C.F.R. § 249.10(a)(5)(i)) and, specifically, what is meant by the language that the services must be sufficient "to reasonably achieve their purpose." *Id.* As explained by the Court, "[t]he answer to this query lies in which such language is interpreted to mean the services must be sufficient to reasonably achieve their purpose for an individual patient or sufficient to reasonably achieve the purpose of the provision of that type of service to the Medicaid population as a whole." *Id.* The Court noted that the "Department of Health, Education and Welfare has interpreted this regulation to mean that services provided reasonably achieve their purpose if the amount, scope and duration would be sufficient for most persons needing that type of care." *Id.* at 785-86. The Secretary of Health, Education and Welfare was a party to the *Kenley* litigation. Subsequently, he relied on an HEW Memorandum stating that, "For example, if a state wishes to limit days of hospital care per year, the number of days should be at least adequate to cover one admission for the average days needed by those individuals covered under the program." *Id.* at 786 (quoting HEW Field Staff Information and Instruction Series: FY-76-62, at 7 (Jan. 2, 1976)).

quired to cover all medically necessary use of an item of care or service included in the State plan.¹²⁷ In many circuits, the standard is, at best, unintelligible.¹²⁸

Among the cases following the approach of Judge Merhige in *Kenley* are *Curtis v. Taylor*, 625 F.2d 645 (5th Cir. 1980) and *Charleston Mem'l Hosp. v. Conrad*, 693 F.2d 324 (4th Cir. 1982). In these cases, the Courts of Appeals upheld limits on inpatient and outpatient hospital coverage that met the medical needs of most of the eligible Medicaid recipients.

¹²⁷ Probably the best example of a jurisdiction in this category is the Eighth Circuit. In *Weaver v. Reagen*, 886 F.2d 194 (8th Cir. 1989), the United States Court of Appeals for the Eighth Circuit invalidated a Missouri Medicaid regulation limiting coverage of AZT (Zidovudine, or Azidothymidine) to those patients with a "medical diagnosis of acquired immunodeficiency syndrome (AIDS) and who have a history of cytologically confirmed *Pneumocystis carinii* pneumonia (PCP) or an absolute CD4 (T4 helper/inducer) lymphocyte count of less than two hundred (200) per cubic millimeter in the peripheral blood before therapy is begun." *Id.* at 196.

Although the Missouri regulation paralleled the FDA approval statement for the drug, numerous physicians in Missouri were prescribing AZT for patients who did not meet the FDA criteria in order to prevent or retard the progression of the disease to a more serious illness. *See id.* at 196-97. The Court acknowledged that this off-label use deviated from the conditions for which the drug was approved but explained that, "[a]ccepted medical practice often includes drug use that is not reflected in approved drug labeling." *Id.* at 198 (citing *Use of Approved Drugs for Unlabeled Indications*, 12 FDA DRUG BULL. 4 (April 1982)). Reaffirming its prior holding in *Pinneke v. Preisser*, 623 F.2d 546 (8th Cir. 1980), the Court stated, "[t]he decision of whether of not certain treatment or a particular type of surgery is 'medically necessary' rests with the individual recipient's physician and not with clerical personnel or government officials." *Id.* at 199 (citing *Pinneke*, 623 F.2d at 550). Missouri, therefore, could not deny coverage of AZT to AIDS patients who were eligible for Medicaid and whose physicians certified that AZT was medically necessary treatment. *See id.* at 200.

¹²⁸ For example, in the Third Circuit, it appears that Medicaid agencies must cover all medically necessary care, but the legal analysis is at best muddled. In *White v. Beal*, 413 F. Supp. 1141 (E.D. Pa. 1976), the district court considered the validity of a Pennsylvania regulation limiting coverage of eyeglasses to those persons with "eye pathology." *Id.* at 1152. The district court invalidated the restriction on several grounds. The Court first held that the restriction violated the first criterion of 45 C.F.R. § 249.10(a)(5)(i) because it did "not provide the amount, scope and duration of services necessary to achieve the purposes stated in the regulations, viz., to improve vision." *Id.* at 1153. Although this conclusion is probably legally correct, the Court did not evaluate the extent to which the provision of eyeglasses met the needs of some Medicaid recipients.

The Court then went on to hold that the Pennsylvania restriction violated the second criterion on 45 C.F.R. § 249.10(a)(5)(i) because it "arbitrarily den[ie]d required services to the categorically needy solely because of a condition — refractive error." *Id.* at 1154. While it is true that the Pennsylvania restriction distinguished based on "the diagnosis, type of illness or condition," that standard only applies "to the required services for the categorically needy." 45 C.F.R. § 249.10(a)(5)(i) (1974) (emphasis added). However, eyeglasses were (and are) an optional service for the categorically needy. *See* 42 U.S.C. § 1396d(a)(12) (1994). The clause prohibiting

discrimination on the basis of "the diagnosis, type of illness or condition," relied on by the district court as an alternate ground for its holding there did not even apply to the Pennsylvania restriction at issue. The district court obscured this point by adding ellipses to its quotation of the relevant section of 42 C.F.R. 249.10(a)(5)(i) ("With respect to the required services for the categorically needy . . .") and by relying on the phrase that is often a red flag to readers: "*It is clear* that eyeglasses are a required service to the categorically needy under the Pennsylvania plan." *White*, 413 F. Supp. at 1154 (emphasis added).

The version of the amount, duration and scope regulation in effect at the time of *White v. Beal* was promulgated in 1974. *See Implementation of Social Security Amendments of 1972 and 1973*, 39 Fed. Reg. 16,969 (1974). That permutation of the regulation contained the following text eliminated in the Court's citation of the section: "With respect to the required services for the categorically needy (*subparagraph (1) of this paragraph*) and the medically needy (*subparagraph (2) of this subparagraph*), the State may not arbitrarily deny or reduce the amount, duration, or scope of such services to an otherwise eligible individual solely because of the diagnosis, type of illness or condition." 45 C.F.R. 249.10(a)(5)(i) (1974) (as promulgated at 39 Fed. Reg. 16,969, 16,971 (1974)) (emphasis added). The language "subparagraph (1) of this paragraph" refers to "the first five items of medical and remedial care and services, as set forth in paragraph (b)(1) through (5) of this section . . ." 45 C.F.R. 249.10(a)(1) (1974). Nowhere in paragraphs (b)(1) through (5) is there any mention of eyeglasses. In fact, eyeglasses only appear as a service in subparagraph (b)(12) making it a service for the categorically needy that could be restricted, consistent with the Medicaid statute, on the basis of diagnosis, type of illness or condition. *See* 45 C.F.R. § 249.10(b)(12) (1974). Similarly, for the medically needy, subparagraph (2) of that paragraph requires states to provide either "[t]he first five items as set forth in paragraph (b)(1) through (5) of this section" or "[a]ny seven of the items as set forth in paragraph (b)(1) through (16) of this section . . ." 45 C.F.R. § 249.10(a)(2)(i) & (ii) (1974) (promulgated at 39 Fed. Reg. 10,971). At the time of *White v. Beal*, Pennsylvania did not provide only the minimum number of services enumerated in 45 C.F.R. 249.10(a)(2). Therefore, the provision of eyeglasses was not required for the medically needy and the provision of eyeglasses could be limited, consistent with the Medicaid statute, on the basis of diagnosis, type of illness or condition. *See id.*

In each of these clauses, I have purposefully inserted the words "consistent with the Medicaid statute." While the district court in *White v. Beal* got it wrong in interpreting Medicaid regulations as it did, its conclusion was arguably also required by section 504 of the Rehabilitation Act of 1973. *See generally* 29 U.S.C.A. § 794 (West 1999 & Supp. 2000) (prohibiting discrimination based on disability by any federally funded program).

Although the district court got its analysis at least half-right, the Court of Appeals for the Third Circuit could not take even that much credit. In affirming the decision of the district court, the Court of Appeals based its decision solely on the ground that, "[t]he regulations permit discrimination in benefits based upon the degree of medical necessity but not upon the medical disorder from which the person suffers." *White v. Beal*, 555 F.2d 1146, 1152 (3rd Cir. 1977). Reaching even further, the Court of Appeals suggested that once a state includes an optional service in its state plan, that service loses its character as an "optional" service and becomes a "required" service for purposes of 45 C.F.R. 249.10(a)(5)(i). *See id.* at n.6 (stating interpretation of regulation by the Regional Commissioner for Social and Rehabilitative Services, HEW). The Court therefore rejected the analysis of the scope of the

Such states as New York have limited the amount, duration, and scope of Viagra coverage.¹²⁹ In New York, Medicaid beneficiaries are limited to a maximum of six tablets per 30 days.¹³⁰ States like New York have therefore probably met the requirements of section 1927 by including Viagra as a covered prescription drug in their Medicaid formularies without covering all medically necessary use of the drug.¹³¹

In her letter to State Medicaid Directors dated November 30, 1998, Sally Richardson, Director of the Center for Medicaid and State Operations, of the Health Care Financing Administration, stated that, "the law requires that a State's Medicaid program cover Viagra when medical necessity dictates such coverage for the drug's medically accepted indication."¹³² Taken literally, that language would impose an obligation on the States

regulation provided by the Regional Commissioner for Social and Rehabilitative Services of HEW in Philadelphia and the plain language of the regulation. *See id.* That error has been repeated by many casual readers of the Medicaid regulations. *See Stewart, supra* note 44, at 616 (stating that the amount, duration, and scope regulation prohibits states from denying coverage of a prescription drug based upon type of illness or condition).

¹²⁹ *See* Letter from Gregor N. Macmillan, *supra* note 100, at 1; *see also* New York Dep't of Health, *supra* note 100. Several other states have imposed similar limits on the amount of Viagra that will be covered. For example, Florida has placed a limit of four Viagra tablets per month that a Medicaid recipient may receive. *See* E-mail from Gary Crayton, Director of Medicaid, Florida Agency for Health Care Admin., to Leidys Dominguez, Research Assistant (July 16, 1999) (copy on file with author); *see also* table *infra* Appendix A (identifying the states' Medicaid coverage plans for Viagra).

¹³⁰ *See* Letter from Gregor N. Macmillan, *supra* note 102; *see also* New York Dep't of Health, *supra* note 102.

¹³¹ This statement assumes that New York has empirical evidence to show that six tablets of Viagra meet the needs of most Medicaid beneficiaries. New York also imposes certain substantive requirements controlling access to Viagra. Viagra can only be prescribed after a physical examination and prescribers must maintain documentation of this examination. A diagnosis of erectile dysfunction is required and the patient must not have a history of using nitrates or any drug containing nitrates within the past 180 days. Prescriptions may be issued for a one-month supply with a maximum of two refills and subsequent prescriptions require a new physical examination by the prescriber. Unlike some other prescribed drugs, early refills and vacation supply requests will not be honored. *See* New York Dep't of Health, *supra* note 102.

¹³² *See* Letter from Sally K. Richardson, *supra* note 99, at 1. The issue of the scope of coverage of Viagra in public and private health insurance plans has been the subject of litigation. *See* Michael Grunwald, *U.S. Judge Asserts Need for More Viagra Coverage*, WASH. POST, Mar. 27, 1999, at A3 (noting that Judge filed a class action suit against HMO claiming it had a duty to cover Viagra as "medically necessary").

to pay for Viagra in any situation in which it is being used for its approved purpose.¹³³ States like New York could not impose an across-the-board six tablets per 30 days limit since some Medicaid beneficiaries might be able to demonstrate a medical need for perhaps eight tablets per 30 days.¹³⁴ The New York limit, therefore, squarely presents the question of whether denial of a medically necessary dosage is legally permissible.¹³⁵

B. Prior Authorization

Another way in which utilization of an item of care or service is controlled is by subjecting the care or service to prior authorization.¹³⁶ Under a prior authorization system, a provider

¹³³ Occasionally, prescription drugs approved by the FDA are prescribed by health care professionals for purposes other than their approved uses. Such a practice is referred to as off-label use. See *An Off-Label Update: Prescribing Drugs for Unapproved Uses*, PEOPLE'S MED. SOC'Y NEWSL., June 1, 1999, at 1 (People's Med. Soc'y, Allentown, Pa.); Michael F. Conlan, *Off-Label, Off-Base: Physicians are Getting Unapproved-Use Data from Manufacturers that is Denied to Pharmacists*, DRUG TOPICS, Feb. 15, 1999, at 57; Meg Stevenson, *Prescriptions: When They're Good for More Than One Ailment*, ACCENT ON LIVING, Fall 1998, at 42; *FDA: To Ease 'Off-Label' Use Restrictions*, AM. HEALTH LINE, June 8, 1998; *Off-Label Use of Drugs an Issue*, CHAIN DRUG REV., Jan. 20, 1997, at Rx6; Diane Debrovner, *Off-Label on Trial*, AM. DRUGGIST, Nov. 1994, at 26. The FDA has attempted to restrict the unapproved uses of approved drugs by prohibiting manufacturers from describing these off-label uses. See Fran Kritz, *FDA Seeks to Add Drugs' New Uses to Labels*, WASH. POST, Mar. 29, 1994, at Z11. Despite this effort, M. Roy Schwarz, a physician and vice-president of science and education for the American Medical Association, estimated that off-label prescribing makes up 40 to 60 percent of all drugs prescribed. See *id.* Most recently, FDA restrictions on the ability of drug manufacturers to describe off-label uses to health care professionals was challenged and invalidated. See also *Washington Legal Found. v. Henney*, 56 F. Supp. 2d 81, 87 (D.D.C. 1999) (holding that the Food and Drug Administration Modernization Act and its implementing regulations unconstitutionally restrict protected commercial speech of drug manufacturers).

¹³⁴ In her letter to State Medicaid Directors, Sally Richardson proposed several measures to control costs, including "plac[ing] limits on the number of refills or the quantity per prescription to discourage waste, fraud, and abuse." Letter from Sally K. Richardson, *supra* note 99, at 2. Absolute limits were not suggested, however. See *id.*

¹³⁵ New York is by no means unique in imposing limits on the availability of Viagra. See table *infra* Appendix A. According to Dr. Mike Magee, Senior Medical Advisor for Pfizer, "[State limits] vary all the way from a low of Georgia, three a month, to unrestricted. Most of them [the states] are coming in at the level of six to eight [tablets per month]." Transcript of Pennsylvania Hearing, *supra* note 36, at 31-32.

¹³⁶ In her letter, Sally Richardson urged states to "[e]stablish prior authorization programs to assure that health professionals meet their responsibilities in prescribing Viagra" Letter from Sally K. Richardson, *supra* note 99, at 2.

of care or service would have to obtain approval from the State Medicaid agency before providing that care or service to a particular patient. Since most Medicaid State agencies now have fully-computerized management systems,¹³⁷ a provider ordinarily must obtain an authorization number to override a computer edit that would otherwise deny payment for the care or service.

Such systems ordinarily require some action by a human being. Since State Medicaid agencies strive to keep personnel costs (and administrative costs generally) to a minimum, a prior authorization model could be utilized for a drug like Viagra. However, because of such costs, use of a prior authorization system will generally be limited to costly services if some non-discretionary model can be utilized.

Section 1927 imposes additional requirements on a State wishing to subject Viagra to prior authorization.¹³⁸ Such a system must provide a "response by telephone or other telecommunication device within 24 hours of a request for prior authorization."¹³⁹ Such a system must also "provide[] for the dispensing of at least a 72-hour supply of a covered outpatient prescription drug in an emergency situation"¹⁴⁰

C. Utilization Review

Utilization review is another way in which States can limit access to care and services in State Medicaid plans.¹⁴¹ Whereas prior authorization takes place before an item of care or service can be provided, utilization review usually takes place after the

¹³⁷ See David F. Chavkin, *An Introduction to the Medicaid Management Information System (MMIS), or Your Friend, the Computer*, 12 CLEARINGHOUSE REV. 99, 102 (1978).

¹³⁸ See section 1927(d)(1)(A) and (d)(5) (42 U.S.C.A. §§ 1396r-8(d)(1)(A) & (d)(5) (West Supp. 2000)).

¹³⁹ Section 1927(d)(5)(A) (42 U.S.C.A. § 1396r-8(d)(5)(A) (West Supp. 2000)).

¹⁴⁰ Section 1927(d)(5)(B) (42 U.S.C.A. § 1396r-8(d)(5)(B) (West Supp. 2000)).

¹⁴¹ Sally Richardson urged that states "[m]onitor and discipline, as appropriate, providers who prescribe Viagra for medically inappropriate indicates or when not medically necessary." Letter from Sally K. Richardson, *supra* note 99, at 2. Section 1396a(a)(30)(A) provides in relevant part that, a State plan for medical assistance must "provide such methods and procedures relating to the utilization of, and the payment for, care and services available under the plan (including but not limited to utilization review plans as provided for in section 1903(i)(4) [42 U.S.C. § 1396b(l)(4)] as may be necessary to safeguard against unnecessary utilization of such care and services" 42 U.S.C.A. § 1396a(a)(30)(A) (West Supp. 2000).

delivery of that care or service. A provider and/or a beneficiary may thereby be placed at risk for denial of reimbursement or other sanctions after the care or service has been provided.¹⁴²

More and more, utilization review is also being done through computer edits.¹⁴³ New York has decided to employ utilization review to control usage of Viagra under the State Medicaid program. All prescriptions for Viagra are subjected to "Drug Utilization Review (DUR)" to ensure that the patient is not currently receiving any contra-indicated drugs.¹⁴⁴ Pfizer has advised health care professionals that Viagra should not be administered to patients using nitrates at any time.¹⁴⁵ When a claim for Medicaid reimbursement of Viagra for a patient is submitted by a pharmaceutical provider, the computer system would examine the patient's record for any prescriptions for any drugs containing nitrates within the past 180 days.¹⁴⁶ Reimbursement for Viagra would then be denied.¹⁴⁷ From a financial standpoint, the State would save money on the non-reimbursed prescription; from a medical standpoint, the patient might or might not be protected from the contraindicated medication

¹⁴² While retroactive denial may pose due process issues, the mere fact of retroactive denial after utilization review has been held not to be a *per se* due process violation. See *Himmler v. Califano*, 611 F.2d 137 (6th Cir. 1979) (upholding retroactive denial of coverage for nursing home care under the Medicare program); see also *Mathews v. Eldridge*, 424 U.S. 319 (1976) (rejecting due process challenge to Social Security Administration policy denying continuing assistance to former beneficiary challenging termination of assistance).

¹⁴³ The Surveillance and Utilization Review (S/UR) Subsystem of the Medicaid Management Information System (MMIS) maintains data on activities and characteristics of individual Medicaid providers and recipients from submitted claims. See Chavkin, *supra* note 137, at 102.

¹⁴⁴ See Letter from Gregor N. Macmillan, *supra* note 102; see also New York Dep't of Health, *supra* note 102, at 3.

¹⁴⁵ "Important Prescribing Information" provided by Pfizer, Inc. to health care professionals states that, "[c]onsistent with its known effects on the nitric oxide/cGMP pathway . . . VIAGRA was shown to potentiate the hypotensive effects of nitrates, and its administration to patients who are using organic nitrates, either regularly and/or intermittently, in any form is therefore contraindicated." *Viagra.com*, *supra* note 32. Nitrates are found in many prescription medicines that are used to treat angina (chest pain due to heart disease) as well as in recreational drugs such as amyl nitrate ("poppers"). See *Patient Summary of Information About Viagra*, *supra* note 32.

¹⁴⁶ See Letter from Gregor N. Macmillan, *supra* note 102, at 1; see also New York Dep't of Health, *supra* note 102.

¹⁴⁷ The denial might actually occur after the Viagra had been dispensed since the computer clearance process does not always happen instantaneously.

since the prescription would already have been dispensed and probably consumed.¹⁴⁸

X. CONCLUSION

The furor over Medicaid coverage of Viagra began to receive national attention when the battle lines were drawn between the federal government and the States in July 1998. Although it was somewhat refreshing to see the federal government unequivocally state that the Medicaid standards governing prescription drugs required State coverage of Viagra, little was done to actually compel compliance by the states with these standards.¹⁴⁹ Several States continue to flout the law.¹⁵⁰ The federal government did, at least, restore some potency to the notion that there are a few absolute standards limiting State discretion in the Medicaid program. At the same time, State claims of dire financial consequences and "unfunded mandates" have proven to be grossly exaggerated and States have been able to comply with federal law without threatening their financial health.¹⁵¹ Ultimately, the tempest over coverage of Viagra has proven to be much ado over very little.

¹⁴⁸ Many pharmacies have their own computerized patient information systems to identify contraindications and side-effects. However, even such a system is not foolproof since it would not reflect problems associated with drugs dispensed through other pharmacies.

¹⁴⁹ In effect, HCFA spoke loudly, but carried no stick. No compliance actions were initiated pursuant to section 1396(c) against states that failed to comply with the Medicaid requirements. See 42 U.S.C. § 1396(c) (1994) (delineating purported requirements for operation of State plans).

¹⁵⁰ See table *infra* Appendix A for a list of the states that, as of the date of the survey, were still not covering Viagra in their state plans.

¹⁵¹ The warnings of some alarmists that the financial sky was literally falling have proven to have little basis in fact. See Stewart, *supra* note 44, at 613-14. "These [impoverished] states, with high percentages of Medicaid eligible persons, should fight the directive through any measures possible to *avoid the devastating cuts in vital health programs that will be necessary to meet the demands for Viagra.*" *Id.* (emphasis added).

APPENDIX A: COVERAGE OF VIAGRA IN STATE MEDICAID PLANS

Alabama	Maximum of 4 tablets per month and requires prior authorization ¹⁵²
Alaska	Excluded from coverage ¹⁵³
Arizona	No restrictions on quantity ¹⁵⁴
Arkansas	Excluded from coverage ¹⁵⁵
California	Maximum of 6 tablets per 30 days ¹⁵⁶
Colorado	Maximum of 6 tablets per 30 days and requires prior authorization ¹⁵⁷

¹⁵² See Letter from Mary H. Finch, Legislative & Media Liaison, Alabama Medicaid Agency, to Leidys Dominguez, Research Assistant (Sept. 15, 1999) (on file with author). See also E-mail from John Searcy, Deputy Commissioner, to Leidys Dominguez, Research Assistant (Sept. 15, 1999) (on file with author); Alabama Medicaid Agency, *Provider Notice No. 99-04* (last modified Jan. 27, 1999) <<http://www.medicaid.state.al.us/bulletin/notices/pn9904.htm>> (on file with author); *Viagra Coverage: Oregon Says 'Yes,' But Not Alabama*, *supra* note 102 (describing efforts by Alabama to limit Medicaid coverage of Viagra).

¹⁵³ See E-mail from Robert B. Labbe, Alaska Medicaid Agency, to Leidys Dominguez, Research Assistant (Sept. 15, 1999) (on file with author). The justification put forward for this exclusion is that, "Viagra . . . is a drug which is used to treat infertility." E-mail from David L. Campana, Pharmacy Program Manager, Alaska Medicaid Agency, to Leidys Dominguez, Research Assistant (Sept. 15, 1999) (on file with author).

¹⁵⁴ See E-mail from Nancy Northrup, Claims Policy Manager, Ariz. Health Care Cost Containment Sys., to Leidys Dominguez, Research Assistant (Sept. 17, 1999) (on file with author); Letter from Leonard A. Jasinski, Medical Director, Arizona Health Care Cost Containment Sys., to Leidys Dominguez, Research Assistant (Sept. 16, 1999) (on file with author).

¹⁵⁵ See E-mail from Ray Hanley, Arkansas Medicaid Agency, to Leidys Dominguez, Research Assistant (Sept. 15, 1999) (on file with author); Official Notice from Ray Hanley, Director, Arkansas Dep't of Hum. Serv., Div. of Med. Serv., to Health Care Providers (July 22, 1998) (No. DMS-98-Q-4, DMS-98-R-11, DMS-98-E-7 (noting that "[u]ntil more information is available Medicaid is temporarily suspending payment for Viagra, effective August 1, 1998")) (on file with author); see also *Viagra: Arkansas Plans to End Medicaid Coverage*, AM. HEALTH LINE, July 24, 1998.

¹⁵⁶ See Letter from Katherine A. Cabacungan, Senior Consulting Pharmacist, State of California Dep't of Health Serv., to Leidys Dominguez, Research Assistant (Sept. 30, 1999) (on file with author).

¹⁵⁷ See COLORADO MEDICAID PRIOR AUTHORIZATION CRITERIA, at 8 (1999) (on file with author).

Connecticut	Maximum of 6 tablets per month ¹⁵⁸
Delaware	Excluded from coverage ¹⁵⁹
District of Columbia	Maximum of 6 tablets per month with prior authorization ¹⁶⁰
Florida	Maximum of 4 doses per month ¹⁶¹
Georgia	Maximum of 3 tablets per month ¹⁶²
Hawaii	Excluded from coverage ¹⁶³
Idaho	Excluded from coverage ¹⁶⁴
Illinois	Maximum of 4 doses per month; approval limited to 3 months ¹⁶⁵

¹⁵⁸ See E-mail from David Parrella, Director, to Leidys Dominguez, Research Assistant (Oct. 1, 1999) (on file with author).

¹⁵⁹ See E-mail from Phillip Soule, Medicaid Director, Delaware Dep't of Health & Soc. Serv., to Leidys Dominguez, Research Assistant (Sept. 28, 1999) (on file with author). In that message, Mr. Soule explains that Delaware excludes coverage on the ground that, "we have found no medically necessary reasons for the use of Viagra." *Id.*

¹⁶⁰ Telephone conversation between Grace Mora, Research Assistant, and Angie Reynolds, Program Assistance, Med. Assistance Admin. Office, Pharmacy Dep't (Feb. 7, 2000).

¹⁶¹ See Agency for Health Care Admin., *Medicaid Services: Pharmacy Notes*, (visited July 7, 1998) <<http://www.fdhc.state.fl.us/medicaid/pharmacy/pharnote.htm>>. "The simple fact is that federal statutes requiring the manufacturer to pay a rebate to Medicaid also require all state Medicaid programs to cover this product." *Id.*; E-mail from Gary Crayton to Leidys Dominguez, Research Assistant (July 16, 1999) (on file with author). In an article describing the Florida coverage of Viagra, the State was criticized for "allow[ing] the impoverished impotent four state-funded liaisons a month . . ." *Yep, Florida's One of 10 States Giving Viagra to Impotent Poor*, *supra* note 112. During the second quarter of 1998, the Florida Medicaid agency paid \$105,020 for about 4,000 Viagra prescriptions dispensed during that period. See *In Brief: Florida Medicaid*, PINK SHEET, Nov. 16, 1998, at 28.

¹⁶² See Lillian Lee Kim, *3 Per Month: Ga. Program to Buy Viagra*, ATLANTA J.-CONST., Sept. 1, 1998, at C3 (indicating that Medicaid coverage will only be extended to males over age 21 with physician approval); Telephone interview by Leidys Dominguez with Etta Hawkins, Georgia Medicaid Agency (Oct. 5, 1999) (transcription on file with author).

¹⁶³ Telephone conversation between Grace Mora, Research Assistant, and Lynn Donovan, Pharmacy Consultant, Med-QUEST Div. (Feb. 8, 2000).

¹⁶⁴ See E-mail from Angela Fink, Idaho Dep't of Health & Welfare, Admin. Procedures Section, to Leidys Dominguez, Research Assistant (Sept. 22, 1999) (on file with author); IDAHO DEPARTMENT OF HEALTH AND WELFARE, WHAT IS MEDICAID? 14 (1999) (stating that Medicaid will not cover prescription drugs unless considered to be medically necessary); cf. *Idaho May Violate Federal Law For Denying Impotence Drug*, *supra* note 37, at 5b.

Indiana	Excluded from coverage ¹⁶⁶
Iowa	Maximum of 4 doses per month ¹⁶⁷
Kansas	Maximum of 10 tablets per month ¹⁶⁸
Kentucky	Maximum of 4 tablets per month with prior authorization ¹⁶⁹
Louisiana	Maximum of 6 tablets per month ¹⁷⁰
Maine	Maximum of 6 tablets with 1 prescription per month ¹⁷¹
Maryland	Maximum of 6 tablets per month with a maximum of 2 refills ¹⁷²
Massachusetts	Prior authorization required; generally limited to 4 tablets per month. ¹⁷³

¹⁶⁵ See E-mail from Marvin Hazelwood, Pharmacy Benefits Manager, Illinois Med. Assistance Program, to Leidys Dominguez, Research Assistant (Sept. 15, 1999) (on file with author).

¹⁶⁶ Prior to terminating coverage, Indiana paid for Viagra for 140 men with a total cost of \$11,400 out of a total Medicaid prescription drug budget of \$2.5 billion. See *Indiana: Medicaid Program Won't Cover Viagra*, AM. HEALTH LINE, June 26, 1998; see also Gelarden, *supra* note 116, at C1. The Indiana Medicaid Agency did not respond to the Fall 1999 survey of state Medicaid agencies.

¹⁶⁷ See E-mail from R. Joe Mahrenholz to Leidys Dominguez, Research Assistant (Oct. 4, 1999) (on file with author).

¹⁶⁸ See E-mail from Karen Braman, Pharmacy Program Manager, Kansas Adult & Med. Serv. Comm'n, to Leidys Dominguez, Research Assistant, (Sept. 16, 1999) (on file with author).

¹⁶⁹ See E-mail from Debra Bahr to Leidys Dominguez, Research Assistant (Sept. 28, 1999) (on file with author). Kentucky requires the physician to submit information on the age of the patient, the patient's history (especially cardiovascular), a complete physical examination to rule out penile deformation, angulation or Peyronie's disease, a review of current medications, a statement that the patient has erectile dysfunction, and whether the patient is a smoker. See *id.*

¹⁷⁰ See Hendren, *supra* note 114, at A3. Louisiana did not respond to the Fall 1999 survey of state Medicaid agencies. However, as of 1998, Viagra was covered under the Louisiana Medicaid program. See 1998 LA. SESS. LAW. SERV. HS. CONC. RES. 48 (West) (limiting Medicaid coverage of sildenafil citrate).

¹⁷¹ Telephone conversation between Grace Mora, Research Assistant, and Donna D. Clerk 3 at the Medicaid Office (Feb. 8, 2000).

¹⁷² See Managed Care Organization Transmittal No. 6 from Joseph M. Millstone, Director, Med. Care Policy Admin., Maryland Med. Assistance Program (Aug. 21, 1998) (on file with author).

¹⁷³ See E-mail from Christopher Burke, Pharmacy Program Analyst, Mass. Div. of Med. Assistance, to Leidys Dominguez, Research Assistant (Sept. 16, 1999) (on file with author). In the fiscal year ended June 30, 1999, the total costs attribut-

Michigan	Excluded from coverage ¹⁷⁴
Minnesota	Prior authorization required; maximum of 6 tablets per month ¹⁷⁵
Mississippi	Maximum of 4 tablets per month with prior authorization ¹⁷⁶
Missouri	Prior authorization required; maximum of 8 tablets per month ¹⁷⁷
Montana	Prior authorization required; maximum of 7 tablets per month ¹⁷⁸
Nebraska	Prior authorization required; maximum of 6 tablets per month ¹⁷⁹
Nevada	Covered without limitation ¹⁸⁰

able to coverage of Viagra were \$2,207 based on a total of 46 prescriptions filled. *See id.* *See also* E-mail from Gary Gilmore, Pharmacist, Massachusetts Div. of Med. Assistance, to Leidys Dominguez, Research Assistant (Sept. 17, 1999) (on file with author) (describing criteria required before Massachusetts Medicaid will cover Viagra).

¹⁷⁴ *See State Resisting Pressure to Pay for Viagra Treatments*, GRAND RAPIDS PRESS, Sept. 12, 1998, at A12 (reporting why Michigan refuses Medicaid coverage of Viagra); *Michigan: Ready to Fight Viagra Medicaid Mandate*, AM. HEALTH LINE, May 29, 1998. Michigan did not respond to the Fall 1999 survey of state Medicaid agencies.

¹⁷⁵ *See* E-mail from Cody C. Wiberg, Acting Pharmacy Program Manager, Minnesota Dep't of Hum. Serv., to Leidys Dominguez, Research Assistant (Sept. 15, 1999) (on file with author); Minnesota Dep't of Hum. Serv., News Release, *State to Provide Provisional Coverage of Viagra Under Medical Assistance (Medicaid) Program* (Sept. 9, 1998) (on file with author); *see also* Maura Lerner, *Minnesota Will Pay for Viagra Through Medicaid Program*, STAR-TRIB. (Minneapolis), Sept. 10, 1998, at 3B; Maura Lerner, *Restrictions on Medicaid Coverage of Viagra Urged*, STAR TRIB. (Minneapolis), Aug. 8, 1998, at B3.

¹⁷⁶ Telephone conversation between Grace Mora, Research Assistant, and Johnnie Price, Medicaid Auditor, Pharmacy Div., Medicaid Program (Feb. 8, 2000).

¹⁷⁷ *See* E-mail from Victormine@aol.com to Leidys Dominguez, Research Assistant (Sept. 15, 1999) (on file with author).

¹⁷⁸ *See* E-mail from Dorothy Poulsen, Montana Dep't of Pub. Health & Serv., Medicaid Serv. Bureau, to Leidys Dominguez, Research Assistant (Sept. 17, 1999) (on file with author).

¹⁷⁹ *See* Ric Compton & Gary Cheloha, Nebraska Health & Hum. Serv. Sys., *Provider Bulletin: Pharmacological Treatment of Sexual Dysfunction: Prior Authorization Requirements* (Dec. 18, 1998) (on file with author).

¹⁸⁰ *See* Letter from April Townley, Deputy Administrator, Nevada Div. of Health Care Financing Policy to Medicaid Providers (Aug. 3, 1998) (on file with

New Hampshire	Excluded from coverage ¹⁸¹
New Jersey	Maximum of 4 tablets per month ¹⁸²
New Mexico	Maximum of 4 tablets per month ¹⁸³
New York	Maximum of 6 tablets per month ¹⁸⁴
North Carolina	Maximum of 2 tablets per month ¹⁸⁵
North Dakota	Covered without limitation ¹⁸⁶
Ohio	Excluded from coverage ¹⁸⁷
Oklahoma	Excluded from coverage ¹⁸⁸
Oregon	Excluded from coverage ¹⁸⁹

author). As noted in the letter, no limitations or prior authorization requirements were established because "the prescription rate of Viagra for Medicaid clients is low." *Id.*

¹⁸¹ See NEW HAMPSHIRE DEPT OF HEALTH & HUM. SERV., MEDICAID SERVICES (Mar. 1998) (stating that coverage of Viagra is excluded as a "medication ... for the purpose of contributing to or enhancing fertility or procreation") (on file with author).

¹⁸² See E-mail from Edward J. Vaccaro, Assistant Director, New Jersey Div. of Med. Assistance & Health Serv., Office of Health Serv. Admin., to Leidys Dominguez, Research Assistant (Oct. 20, 1999) (on file with author).

¹⁸³ See Telephone message by New Mexico Medicaid Agency representative on answering machine of Leidys Dominguez, Research Assistant (Oct. 5, 1999) (copy of transcription of message on file with author).

¹⁸⁴ See New York Dep't of Health, *supra* note 102.

¹⁸⁵ See North Carolina Div. of Med. Assistance, Drug Coverage for Impotence Drugs (effective Mar. 1, 1999) (on file with author). Prior authorization is required for males 44 years old and younger. *See id.*

¹⁸⁶ See E-mail from Rick Detwiller, Administrator, Pharmacy Serv., to Leidys Dominguez, Research Assistant (Oct. 4, 1999) (on file with author). Mr. Detwiller's message also emphasized that, "[u]tilization reports suggest that Viagra usage remains low. *Id.*

¹⁸⁷ See E-mail from Robyn Colby, Medicaid Policy Chief, Office of Medicaid, Ohio Dep't of Hum. Serv., to Leidys Dominguez, Research Assistant (Sept. 29, 1999) (on file with author). However, coverage of Viagra is "still under consideration." *Id.*

¹⁸⁸ Oklahoma is still evaluating coverage. Telephone conversation between Grace Mora, Research Assistant, and John Crumly, Pharmacy Director, Oklahoma Health Care Authority (Feb. 7, 2000).

¹⁸⁹ See E-mail from Beverly Castor, Oregon Dep't of Hum. Serv., Office of Med. Assistance Programs, to Leidys Dominguez (Sept. 20, 1999) (on file with author). Oregon is operating its Medicaid program under a waiver of several federal Medicaid standards pursuant to section 1115 of the Social Security Act, 42 U.S.C. §1315 (1994). *See* Sara Rosenbaum, *Mothers and Children Last: The Oregon Medicaid Experiment*, 18 AM. J.L. & MED. 97 (1992) (evaluating the design of the Medicaid program enacted by Oregon). *See generally* Note, *The Oregon Health Care Proposal and the Americans with Disabilities Act*, 106 HARV. L. REV. 1296 (1993) (de-

Pennsylvania	Maximum of 4 tablets per month with prior authorization ¹⁹⁰
Rhode Island	Prior authorization required; maximum of 8 tablets per month ¹⁹¹
South Carolina	Prior authorization required; maximum of 3 tablets per month ¹⁹²
South Dakota	Excluded from coverage ¹⁹³
Tennessee	Undetermined ¹⁹⁴

scribing the Oregon Plan's interaction with the ADA); W. John Thomas, *The Oregon Medicaid Proposal: Ethical Paralysis, Tragic Democracy, and the Fate of a Utilitarian Health Care Program*, 72 OR. L. REV. 47 (1993) (discussing the innovative Medicaid program enacted by Oregon in 1989). Oregon has prioritized diagnoses or conditions for which funding is available. Impotence falls below the funded line on the prioritized health services list. See E-mail from Beverly Castor, *supra*. This exclusion reflects a change in the number of diagnoses or conditions for which funding was available in 1998. See *Viagra Coverage: Oregon Says 'Yes,' But Not Alabama*, *supra* note 102 (describing coverage of patients whose impotence resulted from organic, rather than psychological causes). The exclusion became the subject of political action by advocates for poor, disabled and older men. See Hopkins Koglin, *supra* note 102, at D1.

¹⁹⁰ Telephone conversation between Grace Mora, Research Assistant, and Joe Concino, Pharmacy Supervisor, Bureau of Policy, Budget & Planning, Pharmacy Serv. Section (Feb. 7, 2000).

¹⁹¹ See E-mail from Paula Avarista to Leidys Dominguez, Research Assistant (Sept. 15, 1999) (on file with author).

¹⁹² See E-mail from James Assey to Leidys Dominguez, Research Assistant (Sept. 16, 1999) (on file with author); Gwen Power, Director, South Carolina Dep't of Health & Hum. Serv., *Special Authorization (SA) Guidelines/Limitations for Pharmaceuticals Indicated for Treatment of Erectile Dysfunction (ED)*, MEDICAID BULL. (Dec. 23, 1998) (on file with author).

¹⁹³ Telephone conversation between Grace Mora, Research Assistant, and Mark Peterson, Pharmacy Consultant, Dep't of Soc. Serv. (Feb. 7, 2000). However, Viagra might be covered through prior authorization on a case-by-case basis. *Id.*

¹⁹⁴ See E-mail from Leo Sullivan, TennCare Pharmacy Director, to Leidys Dominguez, Research Assistant (Oct. 1, 1999) (on file with author). As stated by the Tennessee representative, "all medically necessary drugs are covered by the TennCare MCOs." *Id.* However, there is no indication that Viagra is considered to be "medically necessary" under this program. See Mary Powers, *When Viagra Isn't the Answer; Although New Pill Grabs the Headlines, Other Impotence Treatments are Available*, COMM. APPEAL (Memphis, Tenn.), June 14, 1998, at F1. The Tennessee Medicaid program operates a section 1115 waiver program called TennCare through which Medicaid beneficiaries are placed in a variety of MCOs (medical care organizations). The scope of services and the availability of care vary significantly from plan to plan. For a discussion of the TennCare program, see James F. Blumstein & Frank A. Sloan, *Health Care Reform Through Medicaid Managed Care: Tennessee (TennCare) as a Case Study and a Paradigm*, 53 VAND. L. REV. 125 (2000). See generally Gordon Bonnyman, Jr. & Michele M. Johnson, *Unseen Peril: Inadequate*

Texas	Maximum of 6 tablets per month ¹⁹⁵
Utah	Maximum of 5 tablets per month ¹⁹⁶
Vermont	Prior authorization required; maximum of 4 tablets per month ¹⁹⁷
Virginia	Excluded from coverage ¹⁹⁸
Washington	Covered on a pre-authorization (case-by-case) basis ¹⁹⁹
West Virginia	Prior authorization required; maximum of 6 tablets per month ²⁰⁰
Wisconsin	Excluded from coverage ²⁰¹
Wyoming	Maximum of 6 tablets per month ²⁰²

Enrollee Grievance Protections in Public Managed Care Programs, 65 TENN. L. REV. 359 (1998) (discussing grievance processes in managed care); Judith M. Rosenberg & David T. Zaring, Recent Developments, *Managing Medicaid Waivers: Section 1115 and State Health Care Reform*, 32 HARV. J. ON LEGIS. 545 (1995) (discussing Medicaid waivers and state reform).

¹⁹⁵ See E-mail from Curtis Burch to Leidys Dominguez, Research Assistant (Sept. 17, 1999) (on file with author).

¹⁹⁶ See E-mail from Duane Parke, Utah Medicaid Agency, to Leidys Dominguez, Research Assistant (Sept. 30, 1999) (on file with author). Apparently this maximum represented a reduction by one-half in the coverage previously available. See *Yep, Florida's One of 10 States Giving Viagra to Impotent Poor*, *supra* note 114 (describing a limit of 10 pills per month based on the "normal patterns of men").

¹⁹⁷ See E-mail from Samantha Haley to Leidys Dominguez, Research Assistant (Oct. 20, 1999) (on file with author).

¹⁹⁸ See *Viagra: Virginia Says No, States Fear Federal Mandate*, AM. HEALTH LINE (May 13, 1998) (reporting on exclusion of Viagra from Medicaid coverage). Virginia did not respond to the Fall 1999 survey of state Medicaid agencies.

¹⁹⁹ See E-mail from Siri Childs, Pharmacy Research Specialist, Washington Dep't of Soc. & Health Serv. to Leidys Dominguez, Research Assistant (Sept. 20, 1999) (on file with author).

²⁰⁰ See E-mail from Peggy King to Leidys Dominguez, Research Assistant (Sept. 15, 1999) (on file with author).

²⁰¹ See E-mail from Richard Carr to Leidys Dominguez, Research Assistant (Sept. 22, 1999) (on file with author).

²⁰² Telephone conversation between Grace Mora, Research Assistant, and Roxanne Homar, Medicaid Pharmacist, Health Care Access & Resource Div. (Feb. 7, 2000).

APPENDIX B: SECTION 1927 OF THE SOCIAL SECURITY ACT

§ 1396r-8. Payment for covered outpatient drugs

(a) Requirement for rebate agreement.

(1) **In general.** In order for payment to be available under section 1396b(a) [section 1903(a)] for covered outpatient drugs of a manufacturer, the manufacturer must have entered into and have in effect a rebate agreement described in subsection (b) with the Secretary, on behalf of States (except that, the Secretary may authorize a State to enter directly into agreements with a manufacturer), and must meet the requirements of paragraph (5) (with respect to drugs purchased by a covered entity on or after the first day of the first month that begins after November 4, 1992 [the date of the enactment of title VI of the Veterans Health Care Act of 1992]) and paragraph (6). Any agreement between a State and a manufacturer prior to April 1, 1991, shall be deemed to have been entered into on January 1, 1991, and payment to such manufacturer shall be retroactively calculated as if the agreement between the manufacturer and the State had been entered into on January 1, 1991. If a manufacturer has not entered into such an agreement before March 1, 1991, such an agreement, subsequently entered into, shall become effective as of the date on which the agreement is entered into or, at State option, on any date thereafter on or before the first day of the calendar quarter that begins more than 60 days after the date the agreement is entered into.

(2) **Effective date.** Paragraph (1) shall first apply to drugs dispensed under this subchapter on or after January 1, 1991.

(3) **Authorizing payment for drugs not covered under rebate agreements.** Paragraph (1), and section 1396b(i)(10)(A) [section 1903(i)(10)(A)] of this title, shall not apply to the dispensing of a single source drug or innovator multiple source drug if (A)(i) the State has made a determination that the availability of the drug is essential to the health of beneficiaries under the State plan for medical assistance; (ii) such drug has been given a rating of 1-A by the Food and Drug Administration; and (iii)(I) the physician has obtained approval for use of the drug in advance of its dispensing in accordance with a prior authorization program described in subsection (d), or (II) the Secretary has reviewed and approved the State's determination under subparagraph (A); or (B) the Secretary determines that in the first calendar quarter of 1991, there were extenuating circumstances.

(4) Effect on existing agreements. In the case of a rebate agreement in effect between a State and a manufacturer on November 5, 1990 [the date of the enactment of this section], such agreement, for the initial agreement period specified therein, shall be considered to be a rebate agreement in compliance with this section with respect to that State, if the State agrees to report to the Secretary any rebates paid pursuant to the agreement and such agreement provides for a minimum aggregate rebate of 10 percent of the State's total expenditures under the State plan for coverage of the manufacturer's drugs under this subchapter. If, after the initial agreement period, the State establishes to the satisfaction of the Secretary that an agreement in effect on November 5, 1990, provides for rebates that are at least as large as the rebates otherwise required under this section, and the State agrees to report any rebates under the agreement to the Secretary, the agreement shall be considered to be a rebate agreement in compliance with the section for the renewal periods of such agreement.

(5) Limitation on prices of drugs purchased by covered entities.

(A) Agreement with Secretary. A manufacturer meets the requirements of this paragraph if the manufacturer has entered into an agreement with the Secretary that meets the requirements of section 256b [section 340B of the Public Health Service Act] of this title with respect to covered outpatient drugs purchased by a covered entity on or after the first day of the first month that begins after November 4, 1992 [the date of the enactment of this paragraph].

(B) Covered entity defined. In this subsection, the term "covered entity" means an entity described in section 256b(a)(4) [section 340B(a)(4) of the Public Health Service Act] of this title.

(C) Establishment of alternative mechanism to ensure against duplicate discounts or rebates. If the Secretary does not establish a mechanism under section 256b(a)(5)(A) [section 340B(a)(5)(A) of the Public Health Service Act] within 12 months of November 4, 1992, the following requirements shall apply:

(i) Entities. Each covered entity shall inform the single State agency under section 1396a(a)(5) [section 1902(a)(5)] when it is seeking reimbursement from the State plan for medical assistance described in section 1396d(a)(12) [section 1905(a)(12)] with respect to a unit

of any covered outpatient drug which is subject to an agreement under section 256b(a) [340B(a)] of this title.

(ii) **State agency.** Each such single State agency shall provide a means by which a covered entity shall indicate on any drug reimbursement claims form (or format, where electronic claims management is used) that a unit of the drug that is the subject of the form is subject to an agreement under section 256b [section 340B] of this title, and not submit to any manufacturer a claim for a rebate payment under subsection (b) with respect to such a drug.

(D) Effect of subsequent amendments. In determining whether an agreement under subparagraph (A) meets the requirements of section 256b [340B of the Public Health Service Act] of this title, the Secretary shall not take into account any amendments to such section that are enacted after November 4, 1992 [the enactment of title VI of the Veterans Health Care Act of 1992].

(E) Determination of compliance. A manufacturer is deemed to meet the requirements of this paragraph if the manufacturer establishes to the satisfaction of the Secretary that the manufacturer would comply (and has offered to comply) with the provisions of section 256b [section 340B of the Public Health Service Act] (as in effect immediately after November 4, 1992) and would have entered into an agreement under such section (as such section was in effect at such time), but for a legislative change in such section after November 4, 1992.

(6) Requirements relating to master agreements for drugs procured by Department of Veterans Affairs and certain other Federal agencies.

(A) In general. A manufacturer meets the requirements of this paragraph if the manufacturer complies with the provisions of section 8126 of Title 38 [United States Code], including the requirement of entering into a master agreement with the Secretary of Veterans Affairs under such section.

(B) Effect of subsequent amendments. In determining whether a master agreement described in subparagraph (A) meets the requirements of section 8126 of Title 38 [United States Code], the Secretary shall not take into account any amendments to such section that are enacted after November 4, 1992 [the enactment of title VI of the Veterans Health Care Act of 1992].

(C) Determination of compliance. A manufacturer is deemed to meet the requirements of this paragraph if the manufacturer establishes to the satisfaction of the Secretary that the manufacturer would comply (and has offered to comply) with the provisions of section 8126 of Title 38 [United States Code], (as in effect immediately after November 4, 1992) and would have entered into an agreement under such section (as such section was in effect at such time), but for a legislative change in such section after November 4, 1992.

(b) Terms of rebate agreement.

(1) Periodic rebates.

(A) In general. A rebate agreement under this subsection shall require the manufacturer to provide, to each State plan approved under this subchapter, a rebate for a rebate period in an amount specified in subsection (c) for covered outpatient drugs of the manufacturer dispensed after December 31, 1990, for which payment was made under the State plan for such period. Such rebate shall be paid by the manufacturer not later than 30 days after the date of receipt of the information described in paragraph (2) for the period involved.

(B) Offset against medical assistance. Amounts received by a State under this section (or under an agreement authorized by the Secretary under subsection (a)(1) or an agreement described in subsection (a)(4) of this section) in any quarter shall be considered to be a reduction in the amount expended under the State plan in the quarter for medical assistance for purposes of section 1396b(a)(1) [section 1903(a)(1)] of this title.

(2) State provision of information.

(A) State responsibility. Each State agency under subchapter shall report to each manufacturer not later than 60 days after the end of each rebate period and in a form consistent with a standard reporting format established by the Secretary, information on the total number of units of each dosage form and strength and package size of each covered outpatient drug dispensed after December 31, 1990, for which payment was made under the plan during the period, and shall promptly transmit a copy of such report to the Secretary.

(B) Audits. A manufacturer may audit the information provided (or required to be provided) under subparagraph (A). Adjustments to rebates shall be made to the extent that infor-

mation indicates that utilization was greater or less than the amount previously specified.

(3) Manufacturer provision of price information.

(A) In general. Each manufacturer with an agreement in effect under this section shall report to the Secretary—

(i) not later than 30 days after the last day of each rebate period under the agreement (beginning on or after January 1, 1991), on the average manufacturer price (as defined in subsection (k)(1) of this section) and, (for single source drugs and innovator multiple source drugs), the manufacturer's best price (as defined in subsection (c)(2)(B) of this section) for covered outpatient drugs for the rebate period under the agreement, and

(ii) not later than 30 days after the date of entering into an agreement under this section on the average manufacturer price (as defined in subsection (k)(1) of this section) as of October 1, 1990[,] for each of the manufacturer's covered outpatient drugs.

(B) Verification surveys of average manufacturer price.

The Secretary may survey wholesalers and manufacturers that directly distribute their covered outpatient drugs, when necessary, to verify manufacturer prices reported under subparagraph (A). The Secretary may impose a civil monetary penalty in an amount not to exceed \$100,000 on a wholesaler, manufacturer, or direct seller, if the wholesaler, manufacturer, or direct seller of a covered outpatient drug refuses a request for information about charges or prices by the Secretary in connection with a survey under this subparagraph or knowingly provides false information. The provisions of section 1320a-7a(a) [section 1128A(a)] of this title (other than subsections (a) (with respect to amounts of penalties or additional assessments) and (b)) shall apply to a civil money penalty under this subparagraph in the same manner as such provisions apply to a penalty or proceeding under section 1320a-7a(a) [section 1128A(a)] of this title.

(C) Penalties.

(i) **Failure to provide timely information.** In the case of a manufacturer with an agreement under this section that fails to provide information required under subparagraph (A) on a timely basis, the amount of the penalty shall be increased by \$10,000 for each day in which such infor-

mation has not been provided and such amount shall be paid to the Treasury, and, if such information is not reported within 90 days of the deadline imposed, the agreement shall be suspended for services furnished after the end of the 90-day period and until the date such information is reported (but in no case shall such suspension be for a period of less than 30 days).

(ii) False information. Any manufacturer with an agreement under this section that knowingly provides false information is subject to a civil money penalty in an amount not to exceed \$100,000 for each item of false information. Such civil money penalties are in addition to other penalties as may be prescribed by law. The provisions of section 1320a-7a [section 1128A] (other than subsections (a) and (b)) shall apply to a civil money penalty under this subparagraph in the same manner as such provisions apply to a penalty or proceeding under section 1320a-7a(a) [section 1128A(a)] of this title.

(D) Confidentiality of information. Notwithstanding any other provision of law, information disclosed by manufacturers or wholesalers under this paragraph or under an agreement with the Secretary of Veterans Affairs described in subsection (a)(6)(A)(ii) of this section is confidential and shall not be disclosed by the Secretary or the Secretary of Veterans Affairs or a State agency (or contractor therewith) in a form which discloses the identity of a specific manufacturer or wholesaler, prices charged for drugs by such manufacturer or wholesaler, except—

(i) as the Secretary determines to be necessary to carry out this section,

(ii) to permit the Comptroller General to review the information provided, and

(iii) to permit the Director of the Congressional Budget Office to review the information provided.

(4) Length of agreement.

(A) In general. A rebate agreement shall be effective for an initial period of not less than 1 year and shall be automatically renewed for a period of not less than one year unless terminated under subparagraph (B).

(B) Termination.

(i) By the Secretary. The Secretary may provide for termination of a rebate agreement for violation of the requirements of the agreement or other good cause shown. Such termination shall not be effective earlier than 60 days after the date of notice of such termination. The Secretary shall provide, upon request, a manufacturer with a hearing concerning such a termination, but such hearing shall not delay the effective date of the termination.

(ii) By a manufacturer. A manufacturer may terminate a rebate agreement under this section for any reason. Any such termination shall not be effective until the calendar quarter beginning at least 60 days after the date the manufacturer provides notice to the Secretary.

(iii) Effectiveness of termination. Any termination under this subparagraph shall not affect rebates due under the agreement before the effective date of its termination.

(iv) Notice to States. In the case of a termination under this subparagraph, the Secretary shall provide notice of such termination to the States within not less than 30 days before the effective date of such termination.

(v) Application to terminations of other agreements. The provisions of this subparagraph shall apply to the terminations of agreements described in section 256b(a)(1) [section 340B(a)(1) of the Public Health Service Act] of this title and master agreements described in section 8126(a) of Title 38 [United States Code].

(C) Delay before reentry. In the case of any rebate agreement with a manufacturer under this section which is terminated, another such agreement with the manufacturer (or a successor manufacturer) may not be entered into until a period of 1 calendar quarter has elapsed since the date of the termination, unless the Secretary finds good cause for an earlier reinstatement of such an agreement.

(c) Determination of amount of rebate.

(1) Basic rebate for single source drugs and innovator multiple source drugs.

(A) In general. Except as provided in paragraph (2), the amount of the rebate specified in this subsection for a rebate period (as defined in subsection (k)(8) of this section) with respect to each dosage form and strength of a single source drug

or an innovator multiple source drug shall be equal to the product of—

(i) the total number of units of each dosage form and strength paid for under the State plan in the rebate period (as reported by the State); and

(ii) subject to subparagraph (B)(ii), the greater of— (I) the difference between the average manufacturer price and the best price (as defined in subparagraph (C)) for the dosage form and strength of the drug, or (II) the minimum rebate percentage (specified in subparagraph (B)(i)) of such average manufacturer price, for the rebate period.

(B) Range of rebates required.

(i) **Minimum rebate percentage.** For purposes of subparagraph (A)(ii)(II), the “minimum rebate percentage” for rebate periods beginning— (I) after December 31, 1990, and before October 1, 1992, is 12.5 percent; (II) after September 30, 1992, and before January 1, 1994, is 15.7 percent; (III) after December 31, 1993, and before January 1, 1995, is 15.4 percent; (IV) after December 31, 1994, and before January 1, 1996, is 15.2 percent; and (V) after December 31, 1995, is 15.1 percent.

(ii) **Temporary limitation on maximum rebate amount.** In no case shall the amount applied under subparagraph (A)(ii) for a rebate period beginning— (I) before January 1, 1992, exceed 25 percent of the average manufacturer price; or (II) after December 31, 1991, and before January 1, 1993, exceed 50 percent of the average manufacturer price.

(C) Best price defined. For purposes of this section—

(i) **In general.** The term “best price” means, with respect to a single source drug or innovator multiple source drug of a manufacturer, the lowest price available from the manufacturer during the rebate period to any wholesaler, retailer, provider, health maintenance organization, non-profit entity, or governmental entity within the United States, excluding— (I) any prices charged on or after October 1, 1992, to the Indian Health Service, the Department of Veterans Affairs, a State home receiving funds under section 1741 of Title 38 [United States Code], the Department of Defense, the Public Health Service, or a covered entity described in subsection

(a)(5)(B) of this section; (II) any prices charged under the Federal Supply Schedule of the General Services Administration; (III) any prices used under a State pharmaceutical assistance program; and (IV) any depot prices and single award contract prices, as defined by the Secretary, of any agency of the Federal Government.

(ii) **Special rules.** The term “best price”— (I) shall be inclusive of cash discounts, free goods that are contingent on any purchase requirement, volume discounts, and rebates (other than rebates under this section); (II) shall be determined without regard to special packaging, labeling, or identifiers on the dosage form or product or package; and (III) shall not take into account prices that are merely nominal in amount.

(2) Additional rebate for single source and innovator multiple source drugs.

(A) In general. The amount of the rebate specified in this subsection for a rebate period, with respect to each dosage form and strength of a single source drug or an innovator multiple source drug, shall be increased by an amount equal to the product of—

(i) the total number of units of such dosage form and strength dispensed after December 31, 1990, for which payment was made under the State plan for the rebate period; and

(ii) the amount (if any) by which— (I) the average manufacturer price for the dosage form and strength of the drug for the period, exceeds (II) the average manufacturer price for such dosage form and strength for the calendar quarter beginning July 1, 1990 (without regard to whether or not the drug has been sold or transferred to an entity, including a division or subsidiary of the manufacturer, after the first day of such quarter), increased by the percentage by which the consumer price index for all urban consumers (United States city average) for the month before the month in which the rebate period begins exceeds such index for September 1990.

(B) Treatment of subsequently approved drugs. In the case of a covered outpatient drug approved by the Food and Drug Administration after October 1, 1990, clause (ii)(II) of subparagraph (A) shall be applied by substituting “the first full

calendar quarter after the day on which the drug was first marketed” for “the calendar quarter beginning July 1, 1990” and “the month prior to the first month of the first full calendar quarter after the day on which the drug was first marketed” for “September 1990”.

(3) Rebate for other drugs.

(A) In general. The amount of the rebate paid to a State for a rebate period with respect to each dosage form and strength of covered outpatient drugs (other than single source drugs and innovator multiple source drugs) shall be equal to the product of—

- (i) the applicable percentage (as described in subparagraph (B)) of the average manufacturer price for the dosage form and strength for the rebate period, and
- (ii) the total number of units of such dosage form and strength dispensed after December 31, 1990, for which payment was made under the State plan for the rebate period.

(B) Applicable percentage defined. For purposes of subparagraph (A)(i), the “applicable percentage” for rebate periods beginning—

- (i) before January 1, 1994, is 10 percent, and
- (ii) after December 31, 1993, is 11 percent.

(d) Limitations on coverage of drugs.

(1) Permissible restrictions.

(A) A State may subject to prior authorization any covered outpatient drug. Any such prior authorization program shall comply with the requirements of paragraph (5).

(B) A State may exclude or otherwise restrict coverage of a covered outpatient drug if—

- (i) the prescribed use is not for a medically accepted indication (as defined in subsection (k)(6) of this section);
- (ii) the drug is contained in the list referred to in paragraph (2);
- (iii) the drug is subject to such restrictions pursuant to an agreement between a manufacturer and a State authorized by the Secretary under subsection (a)(1) of this section or in effect pursuant to subsection (a)(4) of this section; or
- (iv) the State has excluded coverage of the drug from its formulary established in accordance with paragraph (4).

(2) List of drugs subject to restriction. The following drugs or classes of drugs, or their medical uses, may be excluded from coverage or otherwise restricted:

- (A) Agents when used for anorexia, weight loss, or weight gain.
- (B) Agents when used to promote fertility.
- (C) Agents when used for cosmetic purposes or hair growth.
- (D) Agents when used for the symptomatic relief of cough and colds.
- (E) Agents when used to promote smoking cessation.
- (F) Prescription vitamins and mineral products, except prenatal vitamins and fluoride preparations.
- (G) Nonprescription drugs.
- (H) 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.
- (I) Barbiturates.
- (J) Benzodiazepines.

(3) Update of drug listings. The Secretary shall, by regulation, periodically update the list of drugs or classes of drugs described in paragraph (2) or their medical uses, which the Secretary has determined, based on data collected by surveillance and utilization review programs of State medical assistance programs, to be subject to clinical abuse or inappropriate use.

(4) Requirements for formularies. A State may establish a formulary if the formulary meets the following requirements:

- (A) The formulary is developed by a committee consisting of physicians, pharmacists, and other appropriate individuals appointed by the Governor of the State (or, at the option of the State, the State's drug use review board established under subsection (g)(3) of this section).
- (B) Except as provided in subparagraph (C), the formulary includes the covered outpatient drugs of any manufacturer which has entered into and complies with an agreement under subsection (a) of this section (other than any drug excluded from coverage or otherwise restricted under paragraph (2)).
- (C) A covered outpatient drug may be excluded with respect to the treatment of a specific disease or condition for an identified population (if any) only if, based on the drug's labeling

(or, in the case of a drug the prescribed use of which is not approved under the Federal Food, Drug, and Cosmetic Act [21 U.S.C.A. §§ 301 et seq.] but is a medically accepted indication, based on information from the appropriate compendia described in subsection (k)(6) of this section), the excluded drug does not have a significant, clinically meaningful therapeutic advantage in terms of safety, effectiveness, or clinical outcome of such treatment for such population over other drugs included in the formulary and there is a written explanation (available to the public) of the basis for the exclusion.

(D) The State plan permits coverage of a drug excluded from the formulary (other than any drug excluded from coverage or otherwise restricted under paragraph (2)) pursuant to a prior authorization program that is consistent with paragraph (5).

(E) The formulary meets such other requirements as the Secretary may impose in order to achieve program savings consistent with protecting the health of program beneficiaries.

A prior authorization program established by a State under paragraph (5) is not a formulary subject to the requirements of this paragraph.

(5) Requirements of prior authorization programs. A State plan under this subchapter may require, as a condition of coverage or payment for a covered outpatient drug for which Federal financial participation is available in accordance with this section, with respect to drugs dispensed on or after July 1, 1991, the approval of the drug before its dispensing for any medically accepted indication (as defined in subsection (k)(6) of this section) only if the system providing for such approval—

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

(B) except with respect to the drugs on the list referred to in paragraph (2), provides for the dispensing of at least 72-hour supply of a covered outpatient prescription drug in an emergency situation (as defined by the Secretary).

(6) Other permissible restrictions. A State may 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 under this chapter.

(e) Treatment of pharmacy reimbursement limits.

(1) In general. During the period beginning on January 1, 1991, and ending on December 31, 1994—

(A) a State may not reduce the payment limits established by regulation under this title or any limitation described in paragraph (3) with respect to the ingredient cost of a covered outpatient drug or the dispensing fee for such a drug below the limits in effect as of January 1, 1991, and

(B) except as provided in paragraph (2), the Secretary may not modify by regulation the formula established under sections 447.331 through 447.334 of title 42, Code of Federal Regulations, in effect on November 5, 1990, to reduce the limits described in subparagraph (A).

(2) Special rule. If a State is not in compliance with the regulations described in paragraph (1)(B), paragraph (1)(A) shall not apply to such State until such State is in compliance with such regulations.

(3) Effect on State maximum allowable cost limitations. This section shall not supersede or affect provisions in effect prior to January 1, 1991, or after December 31, 1994, relating to any maximum allowable cost limitation established by a State for payment by the State for covered outpatient drugs, and rebates shall be made under this section without regard to whether or not payment by the State for such drugs is subject to such a limitation or the amount of such a limitation.

[(4)] Establishment of upper payment limits. HCFA shall establish a Federal upper reimbursement limit for each multiple source drug for which the FDA has rated three or more products therapeutically and additional formulations are rated as such and shall use only such formulations when determining any such upper limit. ...

(g) Drug use review.

(1) In general.

(A) In order to meet the requirement of section 1396b(i)(10)(B) [section 1903(i)(10)(B)] of this title, a State shall provide, by not later than January 1, 1993, for a drug use review program described in paragraph (2) for covered outpatient drugs in order to assure that prescriptions (i) are appropriate, (ii) are medically necessary, and (iii) are not likely to result in adverse medical results. The program shall be designed to educate physicians and pharmacists to identify and reduce the frequency of patterns of fraud, abuse, gross overuse, or inappropriate or medically unnecessary care, among physi-

cians, pharmacists, and patients, or associated with specific drugs or groups of drugs, as well as potential and actual severe adverse reactions to drugs including education on therapeutic appropriateness, overutilization and underutilization, appropriate use of generic products, therapeutic duplication, drug-disease contraindications, drug-drug interactions, incorrect drug dosage or duration of drug treatment, drug-allergy interactions, and clinical abuse/misuse.

(B) The program shall assess data on drug use against predetermined standards, consistent with the following:

(i) compendia which shall consist of the following:

(I) American Hospital Formulary Service Drug Information; **(II)** United States Pharmacopeia-Drug Information; **(III)** the DRUGDEX Information System; and **(IV)** American Medical Association Drug Evaluations; and

(ii) the peer-reviewed medical literature.

(C) The Secretary, under the procedures established in section 1396b [section 1903] of this title, shall pay to each State an amount equal to 75 per centum of so much of the sums expended by the State plan during calendar years 1991 through 1993 as the Secretary determines is attributable to the statewide adoption of a drug use review program which conforms to the requirements of this subsection.

(D) States shall not be required to perform additional drug use reviews with respect to drugs dispensed to residents of nursing facilities which are in compliance with the drug regimen review procedures prescribed by the Secretary for such facilities in regulations implementing section 1396r [section 1919], currently at section 483.60 of title 42, Code of Federal Regulations.

(2) Description of program. Each drug use review program shall meet the following requirements for covered outpatient drugs:

(A) Prospective drug review.

(i) The State plan shall provide for a review of drug therapy before each prescription is filled or delivered to an individual receiving benefits under this subchapter, typically at the point-of-sale or point of distribution. The review shall include screening for potential drug therapy problems due to therapeutic duplication, drug-disease contraindications, drug-drug interactions (including seri-

ous interactions with nonprescription or over-the-counter drugs), incorrect drug dosage or duration of drug treatment, drug-allergy interactions, and clinical abuse/misuse. Each State shall use the compendia and literature referred to in paragraph (1)(B) as its source of standards for such review.

(ii) As part of the State's prospective drug use review program under this subparagraph applicable State law shall establish standards for counseling of individuals receiving benefits under this subchapter by pharmacists which includes at least the following: (I) The pharmacist must offer to discuss with each individual receiving benefits under this subchapter or caregiver of such individual (in person, whenever practicable, or through access to a telephone service which is toll-free for long-distance calls) who presents a prescription, matters which in the exercise of the pharmacist's professional judgment (consistent with State law respecting the provision of such information), the pharmacist deems significant including the following:

(aa) The name and description of the medication.

(bb) The route, dosage form, dosage, route of administration, and duration of drug therapy.

(cc) Special directions and precautions for preparation, administration and use by the patient.

(dd) Common severe side or adverse effects or interactions and therapeutic contraindications that may be encountered, including their avoidance, and the action required if they occur.

(ee) Techniques for self-monitoring drug therapy.

(ff) Proper storage.

(gg) Prescription refill information.

(hh) Action to be taken in the event of a missed dose.

(II) A reasonable effort must be made by the pharmacist to obtain, record, and maintain at least the following information regarding individuals receiving benefits under this subchapter:

(aa) Name, address, telephone number, date of birth (or age) and gender.

(bb) Individual history where significant, including disease state or states, known allergies and drug reactions, and a comprehensive list of medications and relevant devices.

(cc) Pharmacist comments relevant to the individual's drug therapy.

Nothing in this clause shall be construed as requiring a pharmacist to provide consultation when an individual receiving benefits under this title [42 USCS §§ 1396 et seq.] or caregiver of such individual refuses such consultation.

(B) Retrospective drug use review. The program shall provide, through its mechanized drug claims processing and information retrieval systems (approved by the Secretary under section 1396b(r) [section 1903(r)] of this title) or otherwise, for the ongoing periodic examination of claims data and other records in order to identify patterns of fraud, abuse, gross overuse, or inappropriate or medically unnecessary care, among physicians, pharmacists and individuals receiving benefits under this subchapter, or associated with specific drugs or groups of drugs.

(C) Application of standards. The program shall, on an ongoing basis, assess data on drug use against explicit predetermined standards (using the compendia and literature referred to in subsection (1)(B) as the source of standards for such assessment) including but not limited to monitoring for therapeutic appropriateness, overutilization and underutilization, appropriate use of generic products, therapeutic duplication, drug-disease contraindications, drug-drug interactions, incorrect drug dosage or duration of drug treatment, and clinical abuse/misuse and, as necessary, introduce remedial strategies, in order to improve the quality of care and to conserve program funds or personal expenditures.

(D) Educational program. The program shall, through its State drug use review board established under paragraph (3), either directly or through contracts with accredited health care educational institutions, State medical societies or State pharmacists associations/societies or other organizations as specified by the State, and using data provided by the State drug use review board on common drug therapy problems, provide for active and ongoing educational outreach programs (including the activities described in paragraph (3)(C)(iii) of this subsec-

tion) to educate practitioners on common drug therapy problems with the aim of improving prescribing or dispensing practices.

(3) State drug use review board.

(A) Establishment. Each State shall provide for the establishment of a drug use review board (hereinafter referred to as the "DUR Board") either directly or through a contract with a private organization.

(B) Membership. The membership of the DUR Board shall include health care professionals who have recognized knowledge and expertise in one or more of the following:

- (i) The clinically appropriate prescribing of covered outpatient drugs.
- (ii) The clinically appropriate dispensing and monitoring of covered outpatient drugs.
- (iii) Drug use review, evaluation, and intervention.
- (iv) Medical quality assurance.

The membership of the DUR Board shall be made up at least 1/3 but no more than 51 percent licensed and actively practicing physicians and at least 1/3 * * * licensed and actively practicing pharmacists.

(C) Activities. The activities of the DUR Board shall include but not be limited to the following:

- (i) Retrospective DUR as defined in section (2)(B).
- (ii) Application of standards as defined in (2)(C).
- (iii) Ongoing interventions for physicians and pharmacists, targeted toward therapy problems or individuals identified in the course of retrospective drug use reviews performed under this subsection. Intervention programs shall include, in appropriate instances, at least:
 - (I) information dissemination sufficient to ensure the ready availability to physicians and pharmacists in the State of information concerning its duties, powers, and basis for its standards;
 - (II) written, oral, or electronic reminders containing patient-specific or drug-specific (or both) information and suggested changes in prescribing or dispensing practices, communicated in a manner designed to ensure the privacy of patient-related information;
 - (III) use of face-to-face discussions between health care professionals who are experts in rational drug therapy and

selected prescribers and pharmacists who have been targeted for educational intervention, including discussion of optimal prescribing, dispensing, or pharmacy care practices, and follow-up face-to-face discussions; and (IV) intensified review or monitoring of selected prescribers or dispensers.

The Board shall re-evaluate interventions after an appropriate period of time to determine if the intervention improved the quality of drug therapy, to evaluate the success of the interventions and make modifications as necessary.

(D) Annual report. Each State shall require the DUR Board to prepare a report on an annual basis. The State shall submit a report on an annual basis to the Secretary which shall include a description of the activities of the Board, including the nature and scope of the prospective and retrospective drug use review programs, a summary of the interventions used, an assessment of the impact of these educational interventions on quality of care, and an estimate of the cost savings generated as a result of such program. The Secretary shall utilize such report in evaluating the effectiveness of each State's drug use review program.

(h) Electronic claims management.

(1) In general. In accordance with chapter 35 of Title 44 [United States Code] (relating to coordination of Federal information policy), the Secretary shall encourage each State agency to establish, as its principal means of processing claims for covered outpatient drugs under this subchapter, a point-of-sale electronic claims management system, for the purpose of performing on-line, real time eligibility verifications, claims data capture, adjudication of claims, and assisting pharmacists (and other authorized persons) in applying for and receiving payment.

(2) Encouragement. In order to carry out paragraph (1)—

(A) for calendar quarters during fiscal years 1991 and 1992, expenditures under the State plan attributable to development of a system described in paragraph (1) shall receive Federal financial participation under section 1396b(a)(3)(A)(i) [section 1903(a)(3)(A)(i)] of this title (at a matching rate of 90 percent) if the State acquires, through applicable competitive procurement process in the State, the most cost-effective telecommunications network and automatic data processing services and equipment; and

(B) the Secretary may permit, in the procurement described in subparagraph (A) in the application of part 433 of title 42, Code of Federal Regulations, and parts 95, 205, and 307 of title 45, Code of Federal Regulations, the substitution of the State's request for proposal in competitive procurement for advance planning and implementation documents otherwise required.

(i) Annual report.

(1) **In general.** Not later than May 1 of each year the Secretary shall transmit to the Committee on Finance of the Senate, the Committee on Energy and Commerce of the House of Representatives, and the Committees on Aging of the Senate and the House of Representatives a report on the operation of this section in the preceding fiscal year.

(2) **Details.** Each report shall include information on-

(A) ingredient costs paid under this subchapter for single source drugs, multiple source drugs, and nonprescription covered outpatient drugs;

(B) the total value of rebates received and number of manufacturers providing such rebates;

(C) how the size of such rebates compare with the size or [of] rebates offered to other purchasers of covered outpatient drugs;

(D) the effect of inflation on the value of rebates required under this section;

(E) trends in prices paid under this subchapter for covered outpatient drugs; and

(F) Federal and State administrative costs associated with compliance with the provisions of this subchapter.

(j) Exemption of organized health care settings.

(1) Covered outpatient drugs dispensed by health maintenance organizations, including medicaid managed care organizations that contract under section 1396b(m) [section 1903(m)] of this title, are not subject to the requirements of this section.

(2) The State plan shall provide that a hospital (providing medical assistance under such plan) that dispenses covered outpatient drugs using drug formulary systems, and bills the plan no more than the hospital's purchasing costs for covered outpatient drugs (as determined under the State plan) shall not be subject to the requirements of this section.

(3) Nothing in this subsection shall be construed as providing that amounts for covered outpatient drugs paid by the institutions described in this subsection should not be taken into account for purposes of determining the best price as described in subsection (c) of this section.

(k) Definitions. In this section—

(1) **Average manufacturer price.** The term “average manufacturer price” means, with respect to a covered outpatient drug of a manufacturer for a rebate period, the average price paid to the manufacturer for the drug in the United States by wholesalers for drugs distributed to the retail pharmacy class of trade, after deducting customary prompt pay discounts.

(2) **Covered outpatient drug.** Subject to the exceptions in paragraph (3), the term “covered outpatient drug” means—

(A) of those drugs which are treated as prescribed drugs for purposes of section 1396d(a)(12) [section 1905(a)(12)] of this title, a drug which may be dispensed only upon prescription (except as provided in paragraph (5)), and—

(i) which is approved for safety and effectiveness as a prescription drug under section 505 or 507 of the Federal Food, Drug, and Cosmetic Act [21 U.S.C.A. § 355 or 357] or which is approved under section 505(j) of such Act [21 U.S.C.A. § 355(j)];

(ii) (I) which was commercially used or sold in the United States before October 10, 1962 [the date of the enactment of the Drug Amendments of 1962] or which is identical, similar, or related (within the meaning of section 310.6(b)(1) of title 21 of the Code of Federal Regulations) to such a drug, and (II) which has not been the subject of a final determination by the Secretary that it is a “new drug” (within the meaning of section 201(p) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C.A. § 321(p)]) or an action brought by the Secretary under section 301, 302(a), or 304(a) of such Act [21 U.S.C.A. § 331, 332(a), or 334(a)] to enforce section 502(f) or 505(a) of such Act [21 U.S.C.A. § 352(f) or 355(a)]; or

(iii) (I) which is described in section 107(c)(3) of the Drug Amendments of 1962 and for which the Secretary has determined there is a compelling justification for its medical need, or is identical, similar, or related (within the meaning of section 310.6(b)(1) of title 21 of the Code

of Federal Regulations) to such a drug, and (II) for which the Secretary has not issued a notice of an opportunity for a hearing under section 505(e) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C.A. § 355(e)] on a proposed order of the Secretary to withdraw approval of an application for such drug under such section because the Secretary has determined that the drug is less than effective for some or all conditions of use prescribed, recommended, or suggested in its labeling; and

(B) a biological product, other than a vaccine which—

(i) may only be dispensed upon prescription,

(ii) is licensed under section 262 [section 351 of the Public Health Service Act], and

(iii) is produced at an establishment licensed under such section to produce such product; and

(C) insulin certified under section 506 of the Federal Food, Drug, and Cosmetic Act [21 U.S.C.A. § 356].

(3) **Limiting definition.** The term “covered outpatient drug” does not include any drug, biological product, or insulin provided as part of, or as incident to and in the same setting as, any of the following (and for which payment may be made under this subchapter as part of payment for the following and not as direct reimbursement for the drug):

(A) Inpatient hospital services.

(B) Hospice services.

(C) Dental services, except that drugs for which the State plan authorizes direct reimbursement to the dispensing dentist are covered outpatient drugs.

(D) Physicians' services.

(E) Outpatient hospital services.

(F) Nursing facility services and services provided by an intermediate care facility for the mentally retarded.

(G) Other laboratory and x-ray services.

(H) Renal dialysis.

Such term also does not include any such drug or product for which a National Drug Code number is not required by the Food and Drug Administration or a drug or biological used for a medical indication which is not a medically accepted indication. Any drug, biological product, or insulin excluded from the definition of such term as a result of this paragraph shall be treated as a covered outpatient drug

for purposes of determining the best price (as defined in subsection (c)(1)(C) of this section) for such drug, biological product, or insulin.

(4) Nonprescription drugs. If a State plan for medical assistance under this subchapter includes coverage of prescribed drugs as described in section 1396d(a)(12) [section 1905(a)(12)] of this title and permits coverage of drugs which may be sold without a prescription (commonly referred to as “over-the-counter” drugs), if they are prescribed by a physician (or other person authorized to prescribe under State law), such a drug shall be regarded as a covered outpatient drug.

(5) Manufacturer. The term “manufacturer” means any entity which is engaged in—

(A) the production, preparation, propagation, compounding, conversion, or processing of prescription drug products, either directly or indirectly by extraction from substances of natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis, or

(B) in the packaging, repackaging, labeling, relabeling, or distribution of prescription drug products.

Such term does not include a wholesale distributor of drugs or a retail pharmacy licensed under State law.

(6) Medically accepted indication. The term “medically accepted indication” means any use for a covered outpatient drug which is approved under the Federal Food, Drug, and Cosmetic Act [21 U.S.C.A. §§ 301 et seq.] or the use of which is supported by one or more citations included or approved for inclusion in any of the compendia described in subsection (g)(1)(B)(i) of this section.

(7) Multiple source drug; innovator multiple source drug; non-innovator multiple source drug; single source drug.

(A) Defined.

(i) Multiple source drug. The term “multiple source drug” means, with respect to a rebate period, a covered outpatient drug (not including any drug described in paragraph (5)) for which there are 2 or more drug products which— **(I)** are rated as therapeutically equivalent (under the Food and Drug Administration's most recent publication of “Approved Drug Products with Therapeutic Equivalence Evaluations”), **(II)** except as provided in subparagraph (B), are pharmaceutically equivalent and bioequivalent, as defined in subparagraph (C) and as de-

terminated by the Food and Drug Administration, and (III) are sold or marketed in the State during the period.

(ii) **Innovator multiple source drug.** The term “innovator multiple source drug” means a multiple source drug that was originally marketed under an original new drug application approved by the Food and Drug Administration.

(iii) **Noninnovator multiple source drug.** The term “noninnovator multiple source drug” means a multiple source drug that is not an innovator multiple source drug.

(iv) **Single source drug.** The term “single source drug” means a covered outpatient drug which is produced or distributed under an original new drug application approved by the Food and Drug Administration, including a drug product marketed by any cross-licensed producers or distributors operating under the new drug application.

(B) **Exception.** Subparagraph (A)(i)(II) shall not apply if the Food and Drug Administration changes by regulation the requirement that, for purposes of the publication described in subparagraph (A)(i)(I), in order for drug products to be rated as therapeutically equivalent, they must be pharmaceutically equivalent and bioequivalent, as defined in subparagraph (C).

(C) **Definitions.** For purposes of this paragraph—

(i) drug products are pharmaceutically equivalent if the products contain identical amounts of the same active drug ingredient in the same dosage form and meet compendial or other applicable standards of strength, quality, purity, and identity;

(ii) drugs are bioequivalent if they do not present a known or potential bioequivalence problem, or, if they do present such a problem, they are shown to meet an appropriate standard of bioequivalence; and

(iii) a drug product is considered to be sold or marketed in a State if it appears in a published national listing of average wholesale prices selected by the Secretary, provided that the listed product is generally available to the public through retail pharmacies in that State.

(8) **Rebate period.** The term “rebate period” means, with respect to an agreement under subsection (a) of this section, a calendar quarter or other period specified by the Secretary with respect to the payment of rebates under such agreement.

(9) State agency. The term “State agency” means the agency designated under section 1396a(a)(5) [section 1902(a)(5)] of this title to administer or supervise the administration of the State plan for medical assistance.

42 U.S.C.A. § 1396r-8 (West Supp. 2000)