Rules of
Department of Social Services
Division 70—Division of Medical Services
Chapter 20—Pharmacy Program

Title 13—DEPARTMENT OF SOCIAL SERVICES
Division 70—Division of Medical Services
Chapter 20—Pharmacy Program

13 CSR 70-20.010 Participating Drug Vendors

PURPOSE: This rule limits the dispensers of drugs to licensed pharmacists, except in those localities where there are no pharmacies and where it is necessary for a licensed medical practitioner to dispense drugs in order to provide adequate pharmacy service in that community.

(1) Participation in the Missouri drug vendor program shall be limited to duly licensed pharmacies; provided, that licensed authorized medical practitioners may be eligible to participate in the Missouri drug vendor program in the event the Division of Family Services (DFS), in its discretion, determines that participation by practitioners is necessary to insure delivery of pharmacy services to the community. In the localities where there are no pharmacies and the DFS has drug dispensing agreements or would accept these agreements from licensed medical practitioners, the division shall not limit participation to any one (1) licensed medical practitioner if other licensed medical practitioners wish to participate as dispensers of prescription drugs. Those licensed medical practitioners with whom the DFS had a dispensing physician agreement by February 11, 1979, the effective date of this rule, will be exempt from this rule.

AUTHORITY: section 207.020, RSMo 1986. This rule was previously filed as 13 CSR 40-81.011. Original rule filed Nov. 13, 1978, effective Feb. 11, 1979.*

**Original authority: 207.020, RSMo 1945, amended 1961, 1965, 1977, 1981, 1982, 1986.*

13 CSR 70-20.030 Drugs Covered by Medicaid

PURPOSE: This rule implements recent changes in drug coverage as mandated by federal Health Care Financing Administration.

(1) Limiting Definition—As defined in the Social Security Act, section 1927(k)(3), 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 title 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 authorized 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."

(2) Participating Manufacturers—The Missouri Division of Medical Services identifies those manufacturers whose products are reimbursable along with effective dates of coverage, based on date of service, corresponding to effective dates of their participation under the national rebate contract. All products marketed by participating manufacturers are reimbursable, with the following exceptions: those products identified as Drug Efficacy Study Implementation (DESI) drugs by the federal Food and Drug Administration (FDA); products considered by the federal FDA to be similar, identical or related to a DESI product; products identified in 13 CSR 70-20.031 and 13 CSR 70-20.032; and products not meeting the definition of drug in sections 505, 506 and 507 of the federal Food, Drug and Cosmetic Act.

(3) According to the federal Social Security Act, section 1927(a)(1) in order for federal financial participation to be available for covered outpatient drugs of a manufacturer, the manufacturer must have entered into and have in effect a rebate agreement with the secretary of the federal Department of Health and Human Services. States are periodically notified by the federal Health Care Financing Administration of manufacturers that have entered into as well as terminated rebate agreements with the secretary of the federal Department of Health and Human Services. *The Missouri Medicaid Pharmacy Manual* and updating bulletins shall provide the detailed listing of manufacturers that have in effect a rebate agreement with the federal Department of Health and Human Services.

AUTHORITY: section 208.152, 208.153, and 208.201, RSMo. 1994. This rule was previously filed as 13 CSR 40-81.010. Original rule filed Jan. 21, 1964, effective Jan. 31, 1964. Amended: Filed March 30, 1964, effective April 10, 1964. Amended: Filed April 27, 1965, effective May 7, 1965. Amended: Filed Dec. 7, 1966, effective Dec. 17, 1966. Amended: Filed Oct. 11, 1967, effective Oct. 21, 1967. Amended: Filed Oct. 19, 1967, effective Oct. 29, 1967. Amended: Filed Jan. 22, 1968, effective Feb. 2, 1968. Amended: Filed Aug. 24, 1968, effective Sept. 4, 1968. Amended: Filed April 16, 1970, effective April 26, 1970. Amended: Filed Feb. 16, 1971, effective Feb. 26, 1971. Amended: Filed Jan. 3, 1973, effective Jan. 13, 1973. Amended: Filed Feb. 6, 1975, effective Feb. 16, 1975. Amended: Filed March 9, 1977, effective June 11, 1977. Amended: Filed June 13, 1977, effective Oct. 1, 1977. Amended: Filed March 13, 1978, effective June 11, 1978. Amended: Filed Feb. 1, 1979, effective May 11, 1979. Emergency amendment filed July 26, 1979, effective Aug. 1, 1979, expired Oct. 10, 1979. Amended: Filed July 16, 1979, effective Oct. 11, 1979. Emergency amendment filed Aug. 11, 1981, effective Aug. 21, 1981, expired Nov. 11, 1981. Amended: Filed Aug. 11, 1981, effective Nov. 12, 1981. Emergency amendment filed Dec. 21, 1981, effective Jan. 1, 1982, expired April 10, 1982. Emergency amendment filed Jan. 21, 1982, effective Feb. 1, 1982, expired April 10, 1982. Amended: Filed Dec. 21, 1981, effective April 11, 1982. Emergency amendment filed July 22, 1982, effective Aug. 1, 1982, expired Nov. 10, 1982. Amended: Filed July 22, 1982, effective Nov. 11, 1982. Emergency amendment filed Sept. 30, 1982, effective Oct. 10, 1982, expired Jan. 28, 1983. Amended: Filed Jan. 14, 1983, effective May 12, 1983. Amended: Filed July 13, 1983, effective Oct. 13, 1983. Emergency amendment filed Dec. 21, 1983, effective Jan. 1, 1984, expired March 30, 1984. Emergency amendment filed March 21, 1984, effective March 31, 1984, expired July 11, 1984. Amended: Filed March 21, 1984, effective July 12, 1984. Emergency amendment filed April 20, 1984, effective May 1, 1984, expired July 11, 1984. Amended: Filed June 13, 1984, effective Sept. 14, 1984. Amended: Filed Sept. 12, 1984, effective Jan. 12, 1985. Amended: Filed Jan. 15, 1985, effective April 11, 1985. Amended: Filed April 16, 1985, effective July 11, 1985. Amended: Filed Oct. 2, 1985, effective Jan. 1, 1986. Amended: Filed April 16, 1986, effective July 1, 1986. Amended: Filed Sept. 17, 1986, effective Dec. 1, 1986. Amended: Filed Nov. 14, 1986, effective Feb. 12, 1987.*

Emergency amendment filed Dec. 18, 1986, effective Jan. 1, 1987, expired Feb. 11, 1987. Amended: Filed Feb. 18, 1987, effective May 1, 1987. Amended: Filed April 17, 1987, effective July 1, 1987. Amended: Filed June 16, 1987, effective Sept. 1, 1987. Amended: Filed Aug. 18, 1987, effective Nov. 12, 1987. Amended: Filed Dec. 1, 1987, effective Feb. 11, 1988. Amended: Filed April 4, 1988, effective July 1, 1988. Amended: Filed July 15, 1988, effective Oct. 13, 1988. Amended: Filed Sept. 15, 1988, effective Dec. 11, 1988. Amended: Filed April 4, 1989, effective July 1, 1989. Amended: Filed June 6, 1989, effective Sept. 1, 1989. Amended: Filed June 30, 1989, effective Oct. 1, 1989. Amended: Filed Nov. 15, 1989, effective Feb. 1, 1990. Amended: Filed Feb. 16, 1990, effective May 1, 1990. Amended: April 18, 1990, effective June 30, 1990. Amended: Filed Aug. 10, 1990, effective Dec. 31, 1990. Emergency amendment filed Dec. 21, 1990, effective Jan. 1, 1991, expired April 30, 1991. Emergency rescission and rule filed March 21, 1991, effective March 31, 1991, expired July 28, 1991. Emergency rescission filed April 2, 1991, effective April 12, 1991, expired Aug. 9, 1991. Emergency rule filed April 2, 1991, effective April 13, 1991, expired Aug. 10, 1991. Emergency amendment filed June 21, 1991, effective July 1, 1991, expired Aug. 10, 1991. Emergency rescission filed July 31, 1991, effective Aug. 11, 1991, expired Dec. 6, 1991. Rescinded: Filed March 21, 1991, effective Sept. 30, 1991. Emergency rule filed July 31, 1991, effective Aug. 11, 1991, expired Dec. 7, 1991. Readopted: Filed July 15, 1991, effective Jan. 13, 1992. Emergency amendment filed Sept. 23, 1991, effective Oct. 3, 1991, expired Dec. 7, 1991. Emergency rule filed Nov. 27, 1991, effective Dec. 8, 1991, expired April 5, 1992. Emergency amendment filed March 24, 1992, effective April 1, 1992, expired July 29, 1992. Emergency amendment filed June 16, 1992, effective July 1, 1992, expired Oct. 28, 1992. Amended: Filed March 24, 1992, effective Sept. 6, 1992. Emergency amendment filed Sept. 21, 1992, effective Oct. 1, 1992, expired Jan. 28, 1993. Emergency amendment filed Jan. 15, 1993, effective Jan. 29, 1993, expired May 28, 1993. Amended: Filed June 16, 1992, effective April 8, 1993. Emergency amendment filed March 19, 1993, effective April 1, 1993, expired July 29, 1993. Emergency amendment filed June 18, 1993, effective July 1, 1993, expired Oct. 28, 1993. Amended: Filed April 6, 1993, effective Dec. 9, 1993. Rescinded and readopted: Filed Oct. 15, 1993, effective June 6, 1994. Amended: Filed June 29, 2000, effective Dec. 30, 2000.

**Original authority: 208.152, RSMo 1967, amended 1969, 1971, 1972, 1973, 1975, 1977, 1978, 1981, 1986, 1988, 1990, 1992, 1993; 208.153, RSMo 1967, amended 1973, 1989, 1990, 1991 and 208.201, RSMo 1987.*

13 CSR 70-20.031 List of Excludable Drugs for Which Prior Authorization is Required

PURPOSE: This rule establishes a listing of excludable drugs and categories of drugs for which prior authorization is required in order for them to be reimbursable under the Missouri Medicaid Pharmacy Program.

(1) Permissible Exclusions—As specified in the Social Security Act, Section 1927(d)(1)(B), states may exclude or otherwise restrict coverage of certain covered outpatient drugs. Section 1927(d)(2) of the Social Security Act provides a listing of the categories of drugs that are permissible for exclusion. Drugs included on this list may be excluded from coverage entirely or restricted by diagnosis as determined by the state.

(2) As specified in Section 1927(d)(1) of the Social Security Act, states may subject to prior authorization any covered outpatient drug. Any such prior authorization program shall comply with the requirements of Section 1927(d)(5) of the Social Security Act.

(3) List of drugs or categories of excludable drugs which are restricted to require prior authorization for certain specified indications shall be made available through the Department of Social Services, Division of Medical Services website at www.dss.state.mo.us/dms, provider bulletins, and updates to the provider manual.

AUTHORITY: sections 208.153 and 208.201, RSMo 2000. Original rule filed Dec. 13, 1991, effective Aug. 6, 1992. Amended: Filed May 15, 1992, effective Jan. 15, 1993. Amended: Filed March 1, 1996, effective Oct. 30, 1996. Amended: Filed May 27, 1999, effective Dec. 30, 1999. Emergency amendment filed Nov. 21, 2000, effective Dec. 1, 2000, expired May 29, 2001. Amended: Filed June 29, 2000, effective Feb. 28, 2001. Emergency amendment filed filed June 7, 2002, effective July 1, 2002, expired Dec. 27, 2002. Amended: Filed June 11, 2002, effective Jan. 30, 2003.*

**Original authority: 208.153, RSMo 1967, amended 1973, 1989, 1990, 1991 and 208.201, RSMo 1987.*

13 CSR 70-20.032 List of Drugs Excluded From Coverage Under the Missouri Medicaid Pharmacy Program

PURPOSE: This rule establishes a listing of excluded drugs or categories for which reimbursement is not available through the Missouri Medicaid Pharmacy Program.

(1) Permissible Exclusions—As specified in the Social Security Act, Section 1927(d)(1)(B), states may exclude or otherwise restrict coverage of certain covered outpatient drugs. Section 1927(d)(2) of the Social Security Act provides a listing of the categories of drugs that are permissible for exclusion.

(2) List of drugs or classes which are excluded from reimbursement through the Missouri Medicaid Pharmacy Program shall be made available through the Department of Social Services, Division of Medical Services website at www.dss.state.mo.us/dms, provider bulletins, and updates to the provider manual.

AUTHORITY: sections 208.153 and 208.201, RSMo 2000. Original rule filed Dec. 13, 1991, effective Aug. 6, 1992. Amended: Filed June 30, 2000, effective Feb. 28, 2001. Emergency amendment filed June 7, 2002, effective July 1, 2002, expired Dec. 27, 2002. Amended: Filed June 11, 2002, effective Jan. 30, 2003.*

**Original authority: 208.153, RSMo 1967, amended 1973, 1989, 1990, 1991 and 208.201, RSMo 1987.*

13 CSR 70-20.033 Medicaid Program Coverage of Investigational Drugs Used in the Treatment of Acquired Immunodeficiency Syndrome (AIDS)

PURPOSE: This rule establishes, via regulation, the Department of Social Services (DSS)/Division of Medical Services (DMS) guidelines regarding Medicaid coverage and reimbursement for the drug product Serostim used to treat advanced AIDS wasting.

(1) The availability of the drug product Mammalian cell-derived recombinant human growth hormone, r-hGH[m] (Serostim) for Missouri Medicaid coverage shall be limited to only those eligible Medicaid recipients infected with the human immunodeficiency virus (HIV) who meet the eligibility requirements established through the federal Food and Drug Administration under the treatment investigational new drug (TIND) study of this product in adults with AIDS-associated wasting.

(2) Reimbursement for the drug product approved for coverage under the provisions of this rule.

(A) Providers shall be reimbursed for the drug in accordance with the pricing methodology established in 13 CSR 70-20.070.

(B) The drug dispensed shall be subject to the recipient cost-sharing requirements as established in 13 CSR 70-4.051.

AUTHORITY: sections 208.152, 208.153 and 208.201, RSMo 1994. Emergency rule filed Dec. 15, 1995, effective Jan. 1, 1996, expired June 28, 1996. Original rule filed Dec. 15, 1995, effective July 30, 1996.*

**Original authority: 208.152, RSMo 1967, amended 1969, 1972, 1973, 1975, 1977, 1978, 1981, 1986, 1988, 1990, 1992, 1993; 208.153, RSMo 1967, amended 1967, 1973, 1989, 1991; and 208.201, RSMo 1981.*

13 CSR 70-20.034 List of Non-Excludable Drugs for Which Prior Authorization Is Required

PURPOSE: This rule establishes a listing of non-excludable drugs and categories of drugs for which prior authorization is required in order for them to be reimbursable under the Missouri Medicaid Pharmacy Program.

(1) As specified in section 1927(d)(1) of the Social Security Act, states may subject to prior authorization any covered outpatient drug. Any such prior authorization program shall comply with the requirements of section 1927(d)(5) of the Social Security Act.

(2) List of drugs or categories of drugs which are restricted to require prior authorization for certain specified indications shall be made available through the Department of Social Services, Division of Medical Services website at www.dss.state.mo.us/dms, provider bulletins, and updates to the provider manual.

AUTHORITY: sections 208.152, 208.153 and 208.201, RSMo 2000. Emergency rule filed Nov. 21, 2000, effective Dec. 1, 2000, expired May 29, 2001. Original rule filed June 29, 2000, effective Feb. 28, 2001. Emergency amendment filed June 7, 2002, effective July 1, 2002, expired Dec. 27, 2002. Amended: Filed June 11, 2002, effective Jan. 30, 2003.*

**Original authority: 208.152, RSMo 1967, amended 1969, 1971, 1972, 1973, 1975, 1977, 1978, 1978, 1981, 1986, 1988, 1990, 1992, 1993; 208.153, RSMo 1967, amended 1973, 1989, 1990, 1991; and 208.201, RSMo 1987.*

13 CSR 70-20.040 Five Prescription Limit Per Month Per Recipient

PURPOSE: This rule imposes a limitation on the number of prescriptions which may be covered services within a specified time period for each recipient.

(1) The number of prescriptions which may be filled or refilled will be limited to five (5) per recipient during any one (1) period of eligibility which does not exceed the normal monthly eligibility span for the recipient's assistance category involved.

(A) The only allowable exception to the five (5)-prescription limitation will be for certain specified drugs which are commonly prescribed for long-term chronic medical conditions and for prior authorized drugs.

(B) These listed drugs shall be considered to be used for the treatment of long-term chronic medical conditions and shall therefore be exempted from the prescription limitation.

Acebutolol HCl
Acetazolamide
Acetohexamide
Albuterol
Albuterol Sustained Release Tablets
Amantadine HCl
Amiloride HCl and Hydrochlorothiazide Tablets
Amiloride HCl Tablets
Aminophylline
Anhydrous Calcium Iodide and Isoproternal Sulfate Syrup
Atenolol and Chlorthalidone Tablets
Atenolol Tablets
Beclomethasone Dipropionate
Bendroflumethiazide
Bendroflumethiazide and Nadolol Tablets
Benztropine Mesylate
Betaxolol HCl Ophthalmic Solution
Bethanechol Chloride
Biperiden Tablets
Bitolterol Mesylate
Bumetanide Tablets
Captopril and Hydrochlorothiazide Tablets
Captopril Tablets
Carbachol Ophthalmic Solution
Carbamazepine
Carbidopa and Levodopa
Chlorothiazide
Chlorpropamide Tablets
Chlorthalidone and Clonidine HCl
Chlorthalidone Tablets
Cholestyramine
Clofibrate
Clonazepam
Clonidine HCl
Clonidine Transdermal Systems
Codeine Phosphate, Ephedrine Sulfate and Guaifenesin Syrup
Colestipol HCl
Cromolyn Sodium
Demecarium Bromide Ophthalmic Solution
Deserpidine and Methyclothiazide
Dexamethasone Sodium Phosphate Nasal Inhaler
Dexamethasone Sodium Phosphate Oral Inhaler
Dichlorphenamide Tablets
Dicumarol Tablets
Diflunisal
Digitalis
Digitoxin Tablets
Digoxin
Diltiazem HCl
Diltiazem HCl Sustained Release Capsules
Dipivefrin HCl Ophthalmic Solution
Dipyridamole
Disopyramide
Disopyramide Sustained Release Capsules
Dyphylline
Dyphylline and Guaifenesin
Echothiophate Iodide Ophthalmic Solution
Enalapril Maleate
Enalapril Maleate and Hydrochlorothiazide
Encainide HCl
Ephedrine Sulfate Capsules
Ephedrine Sulfate Syrup
Ephedrine Sulfate and Guaifenesin
Epinephrine Ophthalmic Solution
Ergoloid Mesylates Sublingual
Ethacrynic Acid
Ethosuximide
Flecainide
Flunisolide Nasal Spray
Flunisolide Oral Inhaler
Furosemide
Gemfibrozil
Glipizide
Glyburide
Guaifenesin and Oxtriphylline Tablets
Guaifenesin and Phenylpropanolamine HCl Sustained Release Tablets
Guaifenesin and Theophylline Sodium Glycinate Tablets
Guaifenesin and Pseudoephedrine HCl Sustained Release Tablets
Guaifenesin and Theophylline Capsules
Guaifenesin and Theophylline Tablets
Guanabenz Acetate Tablets
Guanadrel Sulfate Tablets
Guanethidine Monosulfate and Hydrochlorothiazide Tablets
Guanethidine Monosulfate Tablets
Guanfacine HCl

Hydralazine
Hydralazine and Hydrochlorothiazide
Hydralazine, Hydrochlorothiazide and Reserpine
Hydrochlorothiazide and Lisinopril
Hydrochlorothiazide and Methyldopa Tablets
Hydrochlorothiazide and Metoprolol Tartrate
Hydrochlorothiazide and Spironolactone Tablets
Hydrochlorothiazide and Timolol
Hydrochlorothiazide and Triamterene
Hydrochlorothiazide Tablets
Hydrochlorothiazide with Labetalol
Hydroflumethiazide and Reserpine
Indapamide Tablets
Indomethacin Suppositories
Insulin
Intravenous Fluids
Dextrose 25%, Sodium Chloride 0.45%
Dextrose 5%
Dextrose 5%, Lactated Ringer's
Dextrose 5%, Sodium Chloride 0.225%
Dextrose 5%, Sodium Chloride 0.3%
Dextrose 5%, Sodium Chloride 0.45%
Dextrose 5%, Sodium Chloride 0.9%
Lactated Ringer's
Sodium Chloride 0.45%
Sodium Chloride 0.9%
Ipatropium Bromide
Isoetharine HCl
Isoflurophate Ophthalmic
Isoproterenol
Isoproterenol and Phenylephrine Bitartrate Oral Inhaler
Isosorbide Dinitrate
Labetalol
Levobunolol HCl Ophthalmic Solution
Levodopa
Levothyroxine Sodium
Lisinopril
Lovastatin
Mecamylamine HCl
Metaproterenol Sulfate
Methazolamide Tablets
Methyclothiazide
Methyldopa
Metolazone
Metoprolol Tartrate
Metyrosine
Mexiletine HCl
Nadolol Tablets
Niacin Tablets
Nicardipine HCl
Nifedipine Capsules
Nifedipine Controlled Release Tablets
Nitroglycerin Spray
Nitroglycerin Sublingual Tablets
Nitroglycerin Sustained Release Capsules
Nitroglycerin Topical Ointment
Nitroglycerin Transdermal Systems
Oxtriphylline
Papaverine HCl Sustained Release 150 mg.
Pentoxifylline
Phenobarbital
Phenytoin
Pilocarpine HCl Ophthalmic Solution
Pindolol
Pirbuterol Acetate
Polythiazide
Potassium Chloride Capsules
Potassium Chloride 10% Liquid
Potassium Chloride 20% Liquid
Potassium Chloride Oral Tablets
Potassium Chloride Sustained Release Capsules
Potassium Chloride Sustained Release Tablets
Prazosin HCl
Primidone
Probucol
Procainamide HCl Capsules
Procyclidine
Propranolol HCl Sustained Release Capsules
Propranolol HCl Tablets
Propylthiouracil
Quinethazone Tablets
Quinidine Sulfate Tablets
Rauwolfia Serpentina Tablets
Reserpine and Trichlormethiazide
Reserpine Tablets
Spironolactone
Syringes, Disposable, Insulin
Terazosin HCl
Terbutaline Sulfate
Theophylline
Theophylline Sustained Release Capsules
Theophylline Sustained Release Tablets
Thyroid Tablets
Timolol Maleate
Tocainide
Tolazamide Tablets
Tolbutamide
Triamcinolone Acetonide Oral Inhaler
Trichlormethiazide
Trihexyphenidyl
Valproic Acid
Valproic Acid, E.C.
Verapamil HCl
Verapamil HCl Sustained Release Tablets
Warfarin Sodium Tablets

AUTHORITY: sections 208.153, RSMo Supp. 1991 and 208.201, RSMo Supp. 1987. This rule was previously filed as 13 CSR 40-81.012. Emergency rule filed Oct. 21, 1981, effective Nov. 1, 1981, expired Feb. 10, 1982. Original rule filed Oct. 21, 1981, effective Feb. 11, 1982. Amended: Filed March 14, 1984, effective June 11, 1984. Amended: Filed June 12, 1984, effective Sept. 14, 1984. Amended: Filed Jan. 15, 1985, effective April 11, 1985. Amended: Filed April 16, 1985, effective July 11, 1985. Amended: Filed Oct. 2, 1985, effective Jan. 1, 1986. Amended: Filed April 16, 1986, effective July 1, 1986. Emergency amendment filed Dec. 18, 1986, effective Jan. 1, 1987, expired Feb. 11, 1987. Amended: Filed Sept. 17, 1986, effective Dec. 1, 1986. Amended: Filed Nov. 14, 1986, effective Feb. 12, 1987. Amended: Filed Feb. 18, 1987, effective May 1, 1987. Emergency amendment filed Dec. 18, 1986, effective Jan. 1, 1987, expired Feb. 11, 1987. Amended: Filed April 17, 1987, effective July 1, 1987. Amended: Filed June 16, 1987, effective Sept. 1, 1987. Amended: Filed Aug. 18, 1987, effective Nov. 12, 1987. Amended: Filed Dec. 1, 1987, effective Feb. 11, 1988. Amended: Filed April 15, 1988, effective July 1, 1988. Amended: Filed July 15, 1988, effective Oct. 13, 1988. Amended: Filed July 15, 1988, effective Oct. 13, 1988. Amended: Filed Sept. 15, 1988, effective Dec. 11, 1988. Amended: Filed April 4, 1989, effective July 1, 1989. Amended: Filed June 6, 1989, effective Sept. 1, 1989. Amended: Filed June 30, 1989, effective Oct. 1, 1989. Amended: Filed Nov. 15, 1989, effective Feb. 1, 1990. Amended: Filed Aug. 13, 1990, effective Dec. 31, 1990. Emergency amendment filed Dec. 21, 1990, effective Jan. 1, 1991, expired April 30, 1991. Emergency amendment filed March 21, 1991, effective April 1, 1991, expired July 29, 1991. Amended: Filed March 13, 1991, effective Oct. 31, 1991.*

**Original authority: 208.153, RSMo 1967, amended 1973, 1989, 1990, 1991 and 208.201, RSMo 1987.*

13 CSR 70-20.045 Thirty-One Day Supply Maximum Restriction on Pharmacy Services Reimbursed by the Division of Medical Services

PURPOSE: The purpose of this is to establish a thirty-one day supply maximum restriction per dispensing on pharmacy services reimbursed by the Division of Medical Services on behalf of patients eligible for any of the fee-for-service programs.

(1) The maximum days supply of medication which may be provided per dispensing on behalf of a patient eligible for any of the fee-for-service programs is thirty-one (31) day supply, except for those drugs and/or categories under the provisions of this rule. Medication may be dispensed in quantities

less than a thirty-one (31) day supply, if so ordered by the prescriber, except as specified elsewhere in this rule.

(2) Drugs and/or categories of medications which are exempt from the thirty-one (31) day supply limitation and therefore may be dispensed in quantities exceeding a thirty-one (31) day supply are as follows:

Drug or Category	Maximum Limitation If Applicable
Antiretroviral Agents	
Contraceptives, Oral	One year
Drug products limited by packaging requirements	Packaging requirements
Vitamins, Children's	100 days
Vitamins, Prenatal	100 days

(3) All spend down recipients are exempt from the Missouri Medicaid thirty-one (31) day supply maximum restriction on pharmacy services.

(4) Exemptions from the thirty-one (31) day supply limitation may be given with prior authorization by the Division of Medical Services to prevent a higher level of care.

AUTHORITY: sections 208.152, 208.153 and 208.201, RSMo 2000. Emergency rule filed Nov. 21, 2000, effective Dec. 1, 2000, expired May 29, 2001. Original rule filed June 29, 2000, effective Feb. 28, 2001. Amended: Filed Dec. 5, 2000, effective June 30, 2001.*

**Original authority: 208.152, RSMo 1967, amended 1969, 1971, 1972, 1973, 1975, 1977, 1978, 1978, 1981, 1986, 1988, 1990, 1992, 1993; 208.153, RSMo 1967, amended 1973, 1989, 1990, 1991; and 208.201, RSMo 1987.*

13 CSR 70-20.050 Return of Drugs

PURPOSE: The Division of Medical Services establishes that when a pharmacy dispenses drugs in a controlled-dose delivery system, the pharmacy must give the Division of Medical Services credit for any unused portion of the drug that is reusable in accordance with applicable federal or state law.

(1) Definitions.

(A) Controlled-dose delivery system. A controlled-dose delivery system is defined as a system of dispensing of medications on behalf of a resident in a long-term care facility in manufacturer's unit dose packaging or pharmacist packager's unit dose, unit-of-use, or strip packaging with each tablet or capsule individually wrapped, or in blister cards, all of which must be dispensed according to applicable state and federal laws or regulations.

(2) Drugs dispensed in controlled-dose delivery system packaging and other drug products which may be returned for reuse per federal and state laws or regulations shall be returned to the dispensing pharmacy in accordance with federal or state laws or regulations when the recipient no longer uses the drug and that product, in the pharmacist's professional judgement may be reused.

(3) The Division of Medical Services shall not pay for an unused pharmacy item returned to the dispensing pharmacy by or on behalf of a Medicaid recipient, due to a change in prescription, hospitalization, death of a recipient, or other reason when the item can be accepted for reuse by the pharmacy in accordance with applicable federal or state laws or regulations.

(4) When a pharmacy dispenses drugs in a controlled-dose delivery system the pharmacy must give the Division of Medical Services credit for all reusable items (any unused portion) not taken by the Medicaid recipient. The Division of Medical Services may provide additional compensation to the pharmacy to recognize administrative costs for processing reusable returned drugs, subject to appropriation. In instances in which charges have been submitted prior to the return of an item the pharmacy shall file an adjustment to notify the Division of Medical Services of the need to process a credit. The dispensing pharmacy that receives the returned drugs must provide a credit to the Division of Medical Services for the amount reimbursed for drug costs from which the prescription was billed, prorated to the quantity of the drug returned. The credited amount should not include dispensing fees.

AUTHORITY: section 208.201, RSMo 2000. Original rule filed Dec. 15, 2000, effective July 30, 2001.*

**Original authority: 208.201, RSMo 1987.*

13 CSR 70-20.060 Professional Dispensing Fee

PURPOSE: The Division of Medical Services establishes the amount of the fee reimbursable for the professional dispensing of each Medicaid-covered prescription by a pharmacy provider, raises the current dispensing fee from two dollars seventy-five cents to three dollars and establishes a long-term care prescription fee add-on.

PUBLISHER'S NOTE: The secretary of state has determined that the publication of the entire text of the material which is incorporated by reference as a portion of this rule would be unduly cumbersome or expensive. Therefore, the material which is so incorporated is on file with the agency who filed this rule, and with the Office of the Secretary of State. Any interested person may view this material at either agency's headquarters or the same will be made available at the Office of the Secretary of State at a cost not to exceed actual cost of copy reproduction. The entire text of the rule is printed here. This note refers only to the incorporated by reference material.

(1) A dispensing fee of three dollars ($3) shall be added to the Medicaid maximum allowable payment for each Missouri Medicaid reimbursable prescription filled or refilled by a pharmacy provider.

(A) The dispensing fee allowed for the dispensing of only those drugs as specified in 13 CSR 70-20.110 for the treatment of acquired immunodeficiency syndrome shall be set at ten percent (10%) of the maximum allowable drug payment.

(B) The professional dispensing fees as provided in this rule shall not be included in the computation of the Missouri Medicaid maximum allowable drug payment for recipient cost-sharing purposes.

(2) All pharmacy providers supplying prescribed Medicaid-covered drugs to recipients in long-term care facilities shall receive an additional fifteen cent (15¢)-dispensing fee per claim provided they—

(A) Dispense medication in a drug distribution system(s) which meets minimum standards of container packaging (at least class B as defined in *United States Pharmacopeia* XXI);

(B) Certify to the Division of Medical Services, on a form and in the manner prescribed by the division, that they—

1. Provide this dispensing service to their long-term care facility resident patients;

2. Provide emergency services twenty-four (24) hours a day with seven (7) days a week availability; and

3. Have ability and willingness to assist in accessing medications through the Medicaid Exception Process; and

(C) Indicate, as prescribed by the Division of Medical Services, on each claim that the prescription was provided in packaging qualifying for the dispensing fee add-on to a recipient in a long-term care facility.

AUTHORITY: sections 208.153, RSMo Supp. 1991 and 208.201, RSMo Supp. 1987. Original rule filed Dec. 15, 1987, effective March 11, 1988.*

**Original authority: 208.153, RSMo 1967, amended 1973, 1989, 1990, 1991 and 208.201, RSMo 1987.*

MISSOURI MEDICAID
LONG TERM CARE PHARMACY DISPENSING FEE
PROVIDER SPECIALTY APPLICATION

PROVIDER INFORMATION

Complete or affix provider label below:

Missouri Medicaid Provider Number _____

Provider Name _____

Provider Address _____

_____

_____

Business telephone _(___)_____

APPLICATION

1. Facilities For Whom You Dispense in Unit-Dose or Controlled-Dose Drug Distribution System Drug Distribution System Name	2. Type of Unit-Dose or Controlled-Dose Drug Distribution System Dispensed in Each Facility
_____	_____
_____	_____
_____	_____
_____	_____
_____	_____
_____	_____
_____	_____
_____	_____
_____	_____
_____	_____

By my signature, I hereby certify that I provide the required distribution system as stated above, and that I provide emergency services and 24 hour a day, seven (7) day a week availability to the long term care facility. In addition, I am able and willing to assist the facility and its residents in accessing medications through the Medicaid exception process.

_____ _____
Provider Signature Date

Return to: Provider Enrollment Unit
Division of Medical Services
P.O. Box 6500
Jefferson City, MO 65102-6500
Telephone No: (314)751-2617

13 CSR 70-20.070 Computer-Generated Drug Pricing Tape and Drug Reimbursement Methodology

PURPOSE: This rule establishes the basis and the method for pricing all drug claims in Missouri under the Title XIX Medicaid program. The purchase of a computer-generated tape, with weekly updates, will make it possible to utilize the computer for review purposes, which greatly increases the speed with which claims can be paid.

PUBLISHER'S NOTE: The publication of the full text of the material that the adopting agency has incorporated by reference in this rule would be unduly cumbersome or expensive. Therefore, the full text of that material will be made available to any interested person at both the Office of the Secretary of State and the office of the adopting agency, pursuant to section 536.031.4, RSMo. Such material will be provided at the cost established by state law.

(1) The Division of Medical Services will obtain, by contract with a reputable medical publishing company, a weekly computer-generated tape which will provide the information needed to price all fee-for-service Medicaid drug claims. The tape will contain *National Drug Code* (NDC), drug name, drug strength, dosage form, package size, the Average Wholesale Price (AWP), the prices set by direct-selling manufacturers (direct prices), Wholesaler Acquisition Cost (WAC), and federal Health and Human Services upper limits for specified multiple source drugs. A multiple source drug is defined as a drug marketed or sold by two (2) or more manufacturers or labelers, or a drug marketed or sold by the same manufacturer or labeler under two (2) or more different proprietary names or both under a proprietary name and without that name.

(2) The Division of Medical Services will add the Missouri Maximum Allowable Cost (MMAC) limits, for multiple source drugs as defined, to the data shown on the tape described in section (1) of this rule.

(3) Reimbursement for covered drugs will be made at the lower of the—

(A) Usual and customary charge as billed by the provider; or

(B) Price(s) included on the Drug Pricing File which is derived from one (1) or more of the following:

1. The AWP as furnished by the state's contracted agent, less ten and forty-three hundredths percent (10.43%);

2. The MMAC as determined by the state agency for selected multiple source drugs;

3. Applicable federal upper limits as found at www.dss.state.mo.us/dms; or

4. The WAC as furnished by the state's contracted agent, plus ten percent (10%).

AUTHORITY: sections 208.152, 208.153, and 208.201, RSMo 2000. This rule was previously filed as 13 CSR 40-81.150. Original rule filed April 23, 1979, effective Aug. 11, 1979. Emergency amendment filed Sept. 9, 1981, effective Oct. 1, 1981, expired Dec. 10, 1981. Amended: Filed Sept. 9, 1981, effective Dec. 11, 1981. Emergency amendment filed Oct. 19, 1987, effective Oct. 29, 1987, expired Feb. 25, 1988. Amended: Filed Dec. 1, 1987, effective Feb. 11, 1988. Emergency amendment filed March 29, 1988, effective April 8, 1988, expired Aug. 5, 1988. Amended: Filed May 3, 1988, effective July 28, 1988. Emergency amendment filed Dec. 21, 1990, effective March 17, 1991, expired April 30, 1991. Emergency amendment filed March 6, 1991, effective March 17, 1991, expired July 14, 1991. Emergency amendment filed Sept. 4, 1991, effective Sept. 17, 1991, expired Jan. 14, 1992. Amended: Filed Sept. 4, 1991, effective Jan. 13, 1992. Amended: Filed Dec. 5, 2000, effective June 30, 2001.*

**Original authority: 208.152, RSMo 1967, amended 1969, 1971, 1972, 1973, 1975, 1977, 1978, 1981, 1986, 1988, 1990, 1992, 1993; 208.153, RSMo 1967, amended 1973, 1989, 1990, 1991; and 208.201, RSMo 1987.*

13 CSR 70-20.071 Multiple Source Drugs for Which There Exists a Federal Upper Limit on Reimbursement

PURPOSE: This rule establishes, via regulation, the Department of Social Services, Division of Medical Services' upper limits on reimbursement for selected multiple source drugs, in response to the implementation of new federal guidelines.

(1) The federal Health Care Financing Administration has established policy that federal matching funds will be provided for certain multiple source drugs, at the appropriate match rate, of an amount not to exceed specified upper limits of reimbursement. The specific upper limits of reimbursement are communicated to state Medicaid agencies periodically, with effective dates designated.

(2) As specified in 13 CSR 70-20.070, reimbursement for multiple source drugs shall be made in an amount not to exceed the federal upper limit, unless prior authorization is obtained by the prescribing physician. Prior authorization must be obtained by telephone or by mailing a completed Drug Prior Authorization Form to the Division of Medical Services to allow reimbursement at the trade name price. The *Medicaid Pharmacy Manual* and updating bulletins shall provide the detailed listing of the specific drug products that shall not be reimbursed in an amount that exceeds the federal upper limit.

AUTHORITY: sections 208.153, RSMo Supp. 1991 and 208.201, RSMo Supp. 1987. Emergency rule filed Oct. 19, 1987, effective Oct. 29, 1987, expired Feb. 25, 1988. Emergency amendment filed Oct. 29, 1987, effective Nov. 8, 1987, expired March 6, 1988. Original rule filed Dec. 1, 1987, effective Feb. 11, 1988. Emergency amendment filed June 21, 1988, effective July 1, 1988, expired Oct. 28, 1988. Amended: Filed Aug. 16, 1988, effective Oct. 29, 1988. Emergency amendment filed May 12, 1989, effective June 1, 1989, expired Sept. 23, 1989. Amended: Filed May 12, 1989, effective Aug. 11, 1989. Amended: Filed Nov. 15, 1989, effective Feb. 1, 1990. Amended: Filed April 18, 1990, effective June 30, 1990. Emergency amendment filed Aug. 20, 1990, effective Sept. 1, 1990, expired Dec. 30, 1990. Amended: Filed Sept. 5, 1990, effective Feb. 14, 1991. Emergency amendment filed Dec. 20, 1990, effective Dec. 31, 1990, expired April 29, 1991. Emergency amendment filed March 21, 1991, effective March 31, 1991, expired July 28, 1991. Amended: Filed April 2, 1991, effective Oct. 31, 1991. Emergency amendment filed Dec. 4, 1992, effective Dec. 15, 1992, expired April 13, 1993. Emergency rescission and emergency rule filed April 2, 1993, effective April 13, 1993, expired Aug. 10, 1993. Amended: Filed Aug. 27, 1993, effective May 9, 1994.*

**Original authority: 208.153, RSMo 1967, amended 1973, 1989, 1990, 1991 and 208.201, RSMo 1987.*

MISSOURI DEPARTMENT OF SOCIAL SERVICES
DIVISION OF MEDICAL SERVICES
DRUG PRIOR AUTHORIZATION

RETURN TO: DIVISION OF MEDICAL SERVICES
P.O. BOX 6500
JEFFERSON CITY, MO 65102
ATTN: EXCEPTION/PHARMACY UNIT

PLEASE PRINT OR TYPE. ALL INFORMATION MUST BE SUPPLIED OR THE REQUEST WILL NOT BE PROCESSED.

1-800-392-8030 FAX: 314-751-2439

☐ INITIAL REQUEST ☐ RENEWAL REQUEST

MEDICAID NUMBER

RECIPIENT NAME

DATE OF BIRTH

DIAGNOSIS (TYPE AND SEVERITY; BE VERYSPECIFIC)

DATE OF ONSET

REQUESTED DRUG NAME, DOSAGE FORM, AND STRENGTH

If the patient has tried or currently takes the requested drug, has it been effective ? ☐ Yes ☐ No

DURATION OF NEED:

Current medications and dosages for this diagnosis, including date started (attach additional sheet if necessary)

If diagnosis is drug-induced, can the source of the condition be eliminated by changing or discontinuing current drug(s)? ☐ Yes ☐ No

All alternative treatments and medications tried, including dates used (attach additional sheet if necessary)

Reason(s) alternative(s) is/are contraindicated

For request for reimbursement for brand name drug: Was generic of requested drug tried? ☐ Yes ☐ No
If yes, state results:

ATTACH ANOTHER SHEET IF ADDITIONAL DOCUMENTATION IS REQUIRED. FOR DRUG-SPECIFIC REQUIREMENTS YOU MAY CALL 1-800-392-8030

REQUESTING PHYSICIAN NAME

TELEPHONE NUMBER

ADDRESS

PHYSICIAN'S SIGNATURE

PROVIDER NUMBER

MO 886-3003 (3-93)

13 CSR 70-20.080 Labeling of Medicaid Prescriptions
(Rescinded December 9, 1993)

AUTHORITY: sections 207.020, RSMo 1986 and 208.153, RSMo Supp. 1991. This rule was previously filed as 13 CSR 40-81.030. Original rule file Oct. 24, 1974, effective Nov. 3, 1974. Rescinded: Filed April 6, 1993, effective Dec. 9, 1993.

13 CSR 70-20.100 Missouri Nonsteroidal Anti-Inflammatory Drug List
(Rescinded September 30, 1991)

AUTHORITY: sections 208.153 and 208.201, RSMo Supp. 1989. This rule was previously filed as 13 CSR 40-81.013. Original rule filed Feb. 18, 1987, effective June 1, 1987. Amended: Filed April 4, 1989, effective July 1, 1989. Amended: Filed Aug. 13, 1990, effective Dec. 31, 1990. Emergency rescission filed March 21, 1991, effective March 31, 1991, expired July 28, 1991. Rescinded: Filed March 21, 1991, effective Sept. 30, 1991.

13 CSR 70-20.110 Medicaid Program Coverage of Approved Drugs for Treatment of Acquired Immunodeficiency Syndrome (AIDS)
(Rescinded September 30, 1991)

AUTHORITY: sections 208.153, RSMo 1986 and 208.201, RSMo Supp. 1988. Emergency rule filed July 9, 1987, effective July 19, 1987, expired Nov. 15, 1987. Original rule filed July 31, 1987, effective Nov. 12, 1987. Amended: Filed Nov. 15, 1989, effective Feb. 1, 1990. Emergency rescission filed March 21, 1991, effective March 31, 1991, expired July 28, 1991. Rescinded: Filed March 21, 1991, effective Sept. 30, 1991.

13 CSR 70-20.120 Medicaid Program Coverage of Anti-Ulcer Preparations
(Rescinded June 29, 1989)

AUTHORITY: sections 208.153, RSMo 1986 and 208.201, RSMo Supp. 1987. Original rule filed Oct. 18, 1988, effective Jan. 1, 1989. Amended: Filed March 16, 1989. Emergency rescission filed April 7, 1989, effective April 20, 1989, expired Aug. 17, 1989. Rescinded: Filed April 7, 1989, effective June 29, 1989.

13 CSR 70-20.200 Drug Prior Authorization Process

PURPOSE: This rule establishes the division process by which drugs may be restricted under Section 4401 of P.L. 101-508 (Omnibus Budget Reconciliation Act of 1990) and are determined to be appropriate for inclusion as a regular benefit of the Missouri Medicaid program or through prior authorization.

(1) The following definitions shall be used in the interpretation and enforcement of this rule:

(A) "Clinical editing" shall be defined as that process which screens the use of specific medications on the basis of clinical appropriateness by requiring evidence of appropriate indications for use, and to achieve a cost savings, may require the initial use of less expensive agents.

(B) "Fiscal editing" shall be defined as a process that screens the use of specific medications to reimburse based on the least expensive dosage forms in order to achieve a cost savings.

(C) "Open access" shall be defined as the availability of a product without being subjected to prior authorization, clinical edits or step therapy but shall not preclude fiscal and utilization edits.

(D) "Preferred Drug List" shall be defined as a list of medications within a functional therapeutic class that are available via open access on the basis of supplemental rebate status and consideration of available evidence-based clinical review findings.

(E) "Step therapy" shall be defined as a process that specifies the sequence in which different prescription drugs are to be reimbursed.

(F) "Utilization edits" are defined as prospective screening edits used to review the appropriate use of medication and may be advisory or preemptory.

(2) This rule establishes a Medicaid Drug Prior Authorization Committee in the Department of Social Services, Division of Medical Services. The committee shall be composed of three (3) practicing physicians licensed pursuant to Chapter 334, RSMo; three (3) practicing pharmacists licensed pursuant to Chapter 338, RSMo, one (1) of whom shall hold a doctoral degree in pharmacy (Pharm. D.); and one (1) registered professional nurse, as defined in Chapter 335, RSMo, practicing in a long-term care setting. All members shall be appointed by the director of the Department of Social Services. The members shall serve for a term of four (4) years. Members of the committee shall receive no compensation for their services, but shall be reimbursed for their actual and necessary expenses incurred, as approved by the Division of Medical Services out of appropriations made for that purpose. The Medicaid Drug Prior Authorization Committee shall meet quarterly. The proposed dates for the meetings shall be announced for one (1) calendar year at the last meeting of the previous calendar year. If a meeting date is changed the new date must be posted at www.dss.mo.gov/dms for at least thirty (30) days prior to the originally scheduled meeting.

(3) All persons eligible for medical assistance benefits shall have access to all pharmaceutical products for which there is federal financial participation except those drugs that may be restricted under Section 4401 of P.L. 101-508 (Omnibus Budget Reconciliation Act of 1990). The Medicaid drug prior authorization committee shall review those drugs that may be restricted and recommend those appropriate for inclusion as a regular benefit of the Missouri Medicaid program or through prior authorization.

(4) The department or the division may require prior authorization of pharmaceutical products. Any such restriction shall be based on medical and clinical criteria, and Missouri-specific data. The committee shall develop this medical and clinical criteria based on predetermined standards consistent with the following:

(A) The American Hospital Formulary Service Drug Information;

(B) The *United States Pharmacopoeia* Drug Information; and

(C) Peer-reviewed medical literature.

(5) If the division finds that the data enumerated in section (4) of this rule has been documented, the Medicaid Drug Prior Authorization Committee shall hold a public hearing prior to making recommendations to the department and prior to any final decision by the division to require prior authorization for that pharmaceutical product, class or category.

(6) The tentative meeting agenda of the Medicaid Drug Prior Authorization Committee with the classes to be discussed shall be posted on the Division of Medical Services website (www.dss.mo.gov/dms) approximately fourteen (14) days prior but no less than seven (7) days prior to the meeting.

(A) The specific therapeutic class or classes to be considered at the next regularly scheduled Medicaid Drug Prior Authorization Committee meeting shall be placed on the current agenda or posted on the website approximately thirty (30) days prior to the scheduled meeting.

(B) Any interested party shall be granted the opportunity for clinically relevant public comment for up to fifteen (15) minutes in the aggregate per medication under review by the

committee. The responsibility of scheduling the presentation shall rest with the manufacturer of the drug product.

(C) Following the consideration of all presented information, the committee shall make their final recommendation to the Division of Medical Services by a majority vote of the members of the committee present thereto in a recorded roll call vote.

(D) The specific therapeutic class or classes recommended for restriction by means of step therapy, clinical edit, fiscal edit or preferred drug list shall be available on the division website at www.dss.mo.gov/dms approximately fifteen (15) calendar days after the meeting.

(7) The recommendations from the Medicaid Drug Prior Authorization Committee shall be referred to the Drug Utilization Review (DUR) Board for placement upon the agenda of the next regularly scheduled meeting. The DUR board may accept or alter the recommendations from the Medicaid Drug Prior Authorization Committee in arriving at their recommendation for the Division of Medical Services. If provided to the division fourteen (14) days in advance of the DUR board meeting, clinically relevant written material shall be presented before the recommendation is considered by the DUR board. The DUR board, at their sole discretion, may entertain clinically relevant public comment up to fifteen (15) minutes in aggregate per medication. The responsibility of scheduling the presentation shall rest with the manufacturer of the drug product. Any changes recommended by the DUR board shall be made available via the approved minutes of the DUR board meeting in a timely fashion, at least thirty (30) days prior to the implementation of the recommendations.

(8) After all recommendations have been reviewed and accepted, the Division of Medical Services staff shall coordinate the implementation of the recommendations. All pertinent information relating to edit schedule and edit criteria shall be made available to the public by reasonable means, including, but not limited to, posting on the division website in a timely fashion following the DUR board meeting. Changes to the Medicaid pharmacy benefit will be posted on a timely basis on the division website. In addition, information on covered medications shall be made available to the public for use with a personal digital assistant device. As determined by the division, patients stabilized on certain restricted medications shall be allowed to access such medication through the Medicaid program for as long as the Medicaid program determines that it is fiscally prudent and clinically supported.

(9) On an annual basis, the Medicaid Drug Prior Authorization Committee shall review all criteria in place, including prior authorization, step therapy, clinical edits, fiscal edits, and the preferred drug list. Annual reviews will be staggered and scheduled to occur at the scheduled meeting closest to completion of a full calendar year after approval of the criteria. If additional clinical or fiscal information is available since the original consideration, interested parties shall have the opportunity to address the committee and request reconsideration of prior authorization, step therapy, clinical edits, fiscal edits, and preferred drug list criteria. All requests shall be scheduled with the division fourteen (14) days in advance of the meeting. All such presentations shall be clinically relevant and limited to a maximum of fifteen (15) minutes. The responsibility of scheduling the presentation shall rest with the manufacturer of the drug product.

(10) The division shall not otherwise restrict the prescribing and dispensing of covered outpatient prescription drugs (other than Drug Efficacy Study Implementation (DESI) drugs as designated by federal law) pursuant to this rule without consulting the Drug Prior Authorization Committee. The division may limit the number of prescriptions allowed for each medical assistance recipient.

(11) As used in the rule, DESI drugs are drugs described in section 107(c)(3) of the Drug Amendments of 1962 and identical, similar or related drugs (within the meaning of section 310.6(b)(1) of Title 21 of the *Code of Federal Regulations*).

(12) When implementing the provisions of section (4), Missouri-specific data shall include the consideration of use and cost data, pharmacoeconomic information and prudent utilization of state funds, and shall include medical and clinical criteria.

AUTHORITY: sections 208.153 and 208.201, RSMo 2000. Original rule filed Feb. 3, 1992, effective Aug. 6, 1992. Emergency amendment filed May 22, 2002, effective June 1, 2002, expired Nov. 27, 2002. Amended: Filed June 3, 2002, effective Nov. 30, 2002. Amended: Filed Dec. 14, 2004, effective June 30, 2005.*

**Original authority: 208.153, RSMo 1967, amended, 1967, 1973, 1989, 1990, 1991 and 208.201, RSMo 1987.*

13 CSR 70-20.250 Prior Authorization of New Drug Entities or New Drug Dosage Form

PURPOSE: This rule outlines the process by which new drugs or new drug dosage forms of existing drugs may be subject to prior authorization prior to payment by the Missouri Medical Assistance Program.

(1) New drug entities, and new drug product dosage forms of existing drug entities, that have been approved by the Food and Drug Administration and are available on the market, shall comply with prior authorization requirements imposed by the division, in compliance with federal law.

(2) Prior authorization restrictions shall continue on new drug entities and new drug product dosage forms of existing drugs until reviewed by the division and the division eliminates the restriction or makes a final determination to require restriction. The division shall consider known cost and use data, medical and clinical criteria, and prudent utilization of state funds in the review. Interested parties may present clinical data to the division's Pharmacy Program Director.

(3) The review referenced in section (2) shall occur within thirty (30) business days after the division receives notice through pricing updates of the availability of the drug entity on the market. Upon completion of the review, the division shall make the drug available for use without prior authorization at that time by all Medicaid recipients or refer the new drug or new drug dosage form to the Medicaid Drug Prior Authorization Committee (MDPAC) with a recommendation for continued prior authorization. During the subsequent review by the MDPAC and Drug Use Review (DUR) Board, the drug shall continue to be available only through prior authorization. Staff recommendations regarding continued prior authorization of a new drug or new drug dosage form shall be made in writing to the MDPAC outlining the criteria used to develop such recommendations. A copy shall be available to the public prior to the MDPAC meeting in which the continued prior authorization is to be discussed.

(4) The MDPAC shall consider any recommendations related to continued prior authorization of a new drug or new drug dosage form at the next scheduled MDPAC meeting. The division and the MDPAC may actively seek comments about the proposed restrictions. The MDPAC shall include a minimum

of fifteen (15) minutes for any interested parties who have notified the division in advance of the scheduled meeting to comment about such proposed restrictions.

(5) If the MDPAC finds that use and cost data, pharmacoeconomic information, along with medical and clinical implications of restriction, are documented and restriction is warranted, the MDPAC shall hold a public hearing regarding the continued restriction and make a recommendation to the division. Such recommendation shall be provided to the division, in writing, prior to the division making a final determination. The division shall provide notice of the final determination through the Department of Social Services, Division of Medical Services website at www.dss.state.mo.us/dms, provider bulletins, and updates to the provider manual.

(6) If, after the hearing referenced in section (5) above, prior authorization of the new drug or new drug dosage form is required, the prior authorization requirement shall be reviewed at least once every twelve (12) months by the MDPAC.

AUTHORITY: sections 208.153 and 208.201, RSMo 2000. Emergency rule filed May 22, 2002, effective June 1, 2002, expired Nov. 27, 2002. Original rule filed June 3, 2002, effective Nov. 30, 2002.*

**Original authority: 208.153, RSMo 1967, amended 1967, 1973, 1989, 1990, 1991 and 208.201, RSMo 1987.*

13 CSR 70-20.300 Retrospective Drug Use Review Process

PURPOSE: This rule establishes the division process by which the Drug Use Review Board will be established as required by Section 4401 of P.L. 101-508 (Omnibus Budget Reconciliation Act of 1990) and by section 208.175, RSMo.

(1) Drug Use Review (DUR) Board. This rule establishes a Medicaid DUR board in the Department of Social Services, Division of Medical Services. The board shall be composed as specified in section 208.175, RSMo.

(2) Members of the DUR board must have the following minimum qualifications:

(A) Must be licensed by Missouri, with that license in active status and in good standing; and

(B) Must have recognized knowledge and expertise in one (1) or more of the following:

1. The clinically appropriate prescribing of covered outpatient drugs;
2. The clinically appropriate dispensing and monitoring of covered outpatient drugs;
3. Drug use review, evaluation and intervention; or
4. Medical quality assurance.

(3) A chairperson shall be elected by the board members.

(4) The board shall meet at least once every ninety (90) days. A quorum of two-thirds (2/3) of the total members, including no fewer than two (2) physicians or two (2) pharmacists, is required for the board to act in its official capacity.

(5) Members shall serve four (4)-year terms, except the terms of the original members, two (2) shall be appointed for a term of two (2) years, three (3) shall be appointed for a term of three (3) years, and three (3) shall be appointed for a term of four (4) years. Members may be reappointed, provided that minimum qualifications for membership continue to be met. Nominations shall be referred for final appointment by the governor subject to advice and consent of the senate. As vacancies occur, the DUR board shall solicit and select a slate of nominees.

(6) The members of the board shall receive no compensation for their services other than reasonable expenses actually incurred in the performance of their official duties.

(7) The DUR board shall provide, either directly or through contracts between the Division of Medical Services and accredited health care schools, state medical societies or state pharmacist associations or societies or other appropriate organizations, provide for educational outreach programs as required by P.L. 101-508, Section 4401, to educate practitioners on common drug therapy problems with the aim of improving, prescribing and dispensing practices. This outreach shall include an educational newsletter to Missouri Medicaid providers including appropriate drug use guidelines and Medicaid utilization statistics.

(8) As specified by P.L. 101-508, Section 4401, the DUR board shall monitor drug use, and prescribing and dispensing practices in the Medicaid program. This monitoring shall include reviewing and refining therapeutic criteria modules used in both retrospective and prospective DUR, as well as overseeing retrospective DUR intervention methods used.

(9) The DUR board shall advise the Department of Social Services regarding all activities associated with the DUR process, including identifying types of intervention methods to be initiated by the review committees, ranging from letters to physicians and pharmacists, face-to-face education and educational symposiums for targeted providers. The board shall provide educational support and guidance as needed by the review committees. The review committees, in turn, shall report intervention results and make recommendations based on these results to the board.

(10) The DUR board shall review and research recommendations from the Prior Authorization Committee, as established by 13 CSR 70-20.200, regarding the advisability of implementing or removing prior authorization requirements for a drug or class of drugs, and make a recommendation to the Department of Social Services.

(11) Specialized DUR Committees. Subject to appropriation, up to six (6) regional review committees may be appointed by the director of the Department of Social Services for the areas surrounding St. Louis, Kansas City, Springfield, Cape Girardeau, Kirksville and Columbia. Other specialized review committees may be formed at the discretion of the Department of Social Services. Members of the review committees shall be physicians and pharmacists appointed by the DUR board, totaling no fewer than five (5) and no more than ten (10) members per committee. A quorum of fifty-one percent (51%) of the total members must be present to conduct business. Regional committee members shall have the same minimum qualifications as required for the DUR board members. Regional committee meetings shall be held every other month. The members of each committee shall elect a chairperson, who shall serve as an ex officio member of the DUR board. Committee members shall receive no compensation other than reasonable expenses actually incurred in the performance of their official duties.

(12) The regional review committees shall conduct patient profile reviews, including opening and closing of cases at the committee meetings. Interventions shall be initiated and follow-up reviews performed by the regional committees. Patterns of inappropriate or aberrant prescribing or dispensing shall be identified and referred to the board in order for targeted education to be formulated.

(13) Agency Responsibility Regarding Confidentiality of Information. All information concerning applicants and recipients of medical services shall be confidential and any disclosure of this information shall be restricted to purposes directly related to the administration of the medical assistance program. Purposes directly related to administration of the medical assistance program include:

(A) Establishing eligibility;

(B) Determining the amount of medical assistance;

(C) Providing services for recipients; and

(D) Conducting or assisting an investigation, prosecution, or civil or criminal proceeding related to the administration of the program.

(14) Provider Responsibility Regarding Confidentiality of Information. All information concerning applicants and recipients of medical services shall be confidential. Any disclosure of this information shall be restricted to purposes directly related to the treatment of the patient and promotion of improved quality of care. The confidential information includes:

(A) Names and addresses;

(B) Social Security number;

(C) Medical services provided;

(D) Social and economic conditions or circumstances;

(E) Medical data, including diagnosis and past history of disease or disability;

(F) Any information received for verifying income eligibility; and

(G) Any information received in connection with the identification of legally liable third-party resources.

AUTHORITY: sections 208.153, RSMo Supp. 1991, 208.175, RSMo Supp. 1993 and 208.201, RSMo Supp. 1987. Original rule filed Dec. 14, 1992, effective June 7, 1993.

**Original authority: 208.153, RSMo 1967, amended 1973, 1989, 1990, 1991; 208.175, RSMo 1992, amended 1993; and 208.201, RSMo 1987.*

13 CSR 70-20.310 Prospective Drug Use Review Process and Patient Counseling

PURPOSE: This rule establishes provisions for prospective drug use review and patient counseling for Medicaid beneficiaries, as required by Section 4401 or Public Law 101-508 (Omnibus Budget Reconciliation Act of 1990) and by section 208.176, RSMo.

(1) Prospective Drug Use Review (DUR). This rule establishes a Medicaid prospective drug use review process within the Department of Social Services, Division of Medical Services, as specified in section 208.176, RSMo.

(2) Electronic Point-of-Sale Review. The Division of Medical Services shall provide for electronic point-of-sale review of drug therapy using predetermined standards before each prescription is dispensed to the non-nursing home Medicaid recipient or Medicaid recipient's caregiver for the current date of service. The process will provide screening for potential drug therapy problems using clinical modules which have been reviewed and approved for use by the Missouri Drug Use Review Board.

(3) Federal Prospective DUR screening requirements for Medicaid beneficiaries. 42 CFR part 456.705(b) requires that the state plan must provide for a point of distribution review of drug therapy using predetermined standards before each prescription is filled or delivered to the recipient or the recipient's caregiver. The review, performed with or without online access to the Pharmacy Point of Service system, must include screening to identify potential drug therapy problems of the following types:

(A) Incorrect drug dosage, that is, the dosage lies outside the daily dosage range specified in predetermined standards as necessary to achieve therapeutic benefit. Dosage range is the strength multiplied by the quantity dispensed divided by days supply;

(B) Adverse drug-drug interaction, that is, the potential for, or occurrence of, an adverse medical effect as a result of the recipient using two (2) or more drugs together;

(C) Drug-disease contraindication, that is the potential for, or occurrence of—

1. An undesirable alteration of the therapeutic effect of a given prescription because of the presence, in the patient for whom it is prescribed, of a disease condition; or

2. An adverse effect of the drug on the patient's disease condition.

(D) Therapeutic duplication, that is, the prescribing and dispensing of two (2) or more drugs from the same therapeutic class so that the combined daily dose puts the recipient at risk of an adverse medical result or incurs additional program costs without additional therapeutic benefit;

(E) Incorrect duration of drug treatment, that is, the number of days of prescribed therapy exceeds or falls short of the recommendations contained in the predetermined standards;

(F) Drug-allergy interactions, that is, the significant potential for, or the occurrence of, an allergic reaction as a result of drug therapy; and

(G) Clinical abuse/misuse, that is, the occurrence of situations referred to in the definitions of abuse, gross overuse, overutilization and underutilization, as defined in 42 CFR 456.702, and incorrect dosage and incorrect duration, as defined in subsections (3)(A) and (E) of this rule.

(4) Screens Available for Medicaid Beneficiaries. The following screens will be provided by the Pharmacy Point of Service system:

(A) Drug Disease Contraindications.

1. Drug (actual) disease precaution.

2. Inferred Drug Disease precaution;

(B) Drug to Drug Interactions;

(C) Side Effects.

1. Additive toxicity side effects.

2. Medical condition/additive side effect.

3. Side effect.

4. Drug indicated for side effect of previously prescribed drug;

(D) Dose Range Checking.

1. High dose alert.

2. Low dose alert;

(E) Minimum/Maximum Daily Dose.

1. High dose alert.

2. Low dose alert;

(F) Duplicate Therapy Checking.

1. Therapeutic duplication.

2. Ingredient duplication; and

(G) Duration of Therapy (H2).

1. Excessive duration alert.

(5) Medicaid Patient Counseling. As part of the prospective DUR program, participating pharmacies shall perform Medicaid patient counseling according to the standards established by the Board of Pharmacy under 4 CSR 220-2.190.

(6) Medicaid Patient Profiles. The term, reasonable effort means that each time a Medicaid patient or caregiver presents a prescription, the pharmacist or pharmacist's designee should request profile information verbally or in writing. For example, if the patient presents the prescription in person, the request should be make verbally, and if the prescription is received by mail, the request should be made in writing. This does not imply that the service should be denied solely on the basis of the patient's refusal to supply this information. Pharmacies must make a reasonable effort to obtain records and maintain patient profiles containing, at a minimum:

(A) The name, address, telephone number, date of birth (or age) and gender of the patient;

(B) Individual medical history, if significant, including disease states, known allergies and drug reactions, and a comprehensive list of medications and relevant devices; and

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

(7) Documentation of Offer to Counsel. The pharmacist shall document for each Medicaid patient's prescription in a uniform fashion, whether the offer to counsel was accepted or refused by the patient or the patient's agent.

(8) Agency Responsibility Regarding Confidentiality of Information. All information concerning applicants and recipients of medical services shall be kept confidential by the Division of Medical Services, and any disclosure of this information shall be restricted to purposes directly related to the administration of the medical assistance program. Purposes directly related to administration of the medical assistance program include:

(A) Establishing eligibility;

(B) Determining the amount of medical assistance;

(C) Providing services for recipients; and

(D) Conducting or assisting an investigation, prosecution, or civil or criminal proceeding related to the administration of the program.

(9) Provider Responsibility Regarding Confidentiality of Medicaid Beneficiary Information. All information concerning applicants and recipients of medical services shall be confidential. Any disclosure of this information by the pharmacy provider shall be restricted to purpose directly related to the treatment of the patient and promotion of improved quality of care, or conducting or assisting an investigation, prosecution, or civil or criminal proceeding related to the administration of the program. The confidential information includes:

(A) Names and addresses;

(B) Social Security number;

(C) Medical services provided;

(D) Social and economic conditions or circumstances;

(E) Medical data, including diagnosis and past history of disease or disability;

(F) Any information received for verifying income eligibility; and

(G) Any information received in connection with the identification of legally liable third party resources.

AUTHORITY: sections 208.153, RSMo Supp. 1991 and 208.201 RSMo Supp. 1987. Original rule filed June 3, 1993, effective Dec. 9, 1993.*

**Original authority: 208.153, RSMo 1967, amended 1973, 1989, 1990, 1991 and 208.201, RSMo 1987.*

13 CSR 70-20.320 Pharmacy Reimbursement Allowance

PURPOSE: This rule establishes a Pharmacy Federal Reimbursement Allowance and the methodologies to determine the formula for the amount of allowance each pharmacy is required to pay for the privilege of providing outpatient prescription drugs.

(1) Pharmacy Reimbursement Allowance (PRA). PRA shall be assessed as described in this section.

(A) Definitions.

1. Department—Department of Social Services.

2. Director—Director of Department of Social Services.

3. Division—Division of Medical Services.

4. Monthly gross retail prescription receipts—For ease of administration for the department as well as the industry, this shall be an annual amount. The basis of tax in any fiscal year will be the gross prescription sales of the last calendar year prior to the previous fiscal year.

(B) Each pharmacy engaging in the business of providing outpatient prescription drugs in Missouri to the general public shall pay a PRA.

1. The PRA owed for existing pharmacies shall be calculated by multiplying the pharmacy's total gross retail prescription receipts by the tax rate determined by the department. Subject to the limitations established in section 538.520, RSMo, the range of such said tax rate shall be uniformly distributed in bands determined by a ratio of total Medicaid prescriptions divided by total sales and shall not exceed six percent (6%).

2. The PRA shall be divided by and collected over the number of months for which the PRA is effective.

3. The initial PRA owed by a newly licensed pharmacy shall be calculated by estimating the total prescription sales and multiplying the estimate by the rate determined by the department.

4. If a pharmacy ceases to provide outpatient prescription drugs to the general public, the pharmacy is not required to pay the PRA during the time it did not provide outpatient prescription drugs.

5. If the pharmacy reopens, it shall resume paying the PRA. It shall owe the same PRA as it did prior to closing, if the PRA has not changed per paragraph (1)(B)1.

(C) Each pharmacy shall submit an affidavit to the department with the following information:

1. Pharmacy name;

2. Contact;

3. Telephone number;

4. Address;

5. Federal tax ID number;

6. Medicaid pharmacy number (if applicable);

7. Pharmacy sales (total);

8. Medicaid pharmacy sales;

9. Number of paid Medicaid prescription; and

10. Gross receipts attributable to prescription drugs that are delivered directly to the patient via common carrier, by mail, or a courier service.

(D) The department shall prepare a confirmation schedule of the information provided by each pharmacy and the amount of PRA that is due from the pharmacy.

(E) Each pharmacy shall review the information prepared by the department and the amount of PRA calculated by the department to verify that the information is correct.

1. If the information supplied by the department is incorrect, the facility, within thirty (30) calendar days of receiving the confirmation schedule must notify the division and explain the correction.

2. If the division does not receive corrected information within thirty (30) calendar days, it will be assumed to be correct, unless the pharmacy files a protest in accordance with subsection (2)(D) of this regulation.

(2) Payment of the PRA.

(A) Offset.

1. Each pharmacy may request that its PRA offset against any Missouri Medicaid payment due to that pharmacy.

A. A statement authorizing the offset must be on file with the division before any offset may be made relative to the PRA by the pharmacy.

B. Assessments shall be allocated and deducted over the applicable service period.

C. Any balance due after the offset shall be remitted to the Director of the Department of Revenue and be deposited in the state treasury to the credit of the Pharmacy Reimbursement Allowance Fund.

D. If the remittance is not received before the next Medicaid payment cycle, the division shall offset the balance due from that check.

(B) Check.

1. If no offset has been authorized by the pharmacy, the division will begin collecting the pharmacy reimbursement allowance on the first day of each month for the preceding months.

2. The PRA shall be remitted by the pharmacy to the department. The remittance shall be made payable to the Director of the Department of Revenue and be deposited in the state treasury to the credit of the Pharmacy Reimbursement Allowance Fund.

(C) Failure to comply with this request for information or failure to pay the PRA.

1. If a pharmacy fails to comply with a request for information from the Division of Medical Services or fails to pay its PRA within thirty (30) days of notice, the PRA shall be delinquent.

2. For any delinquent PRA, the department may:

A. Proceed to enforce the state's lien of the property of the pharmacy;

B. Cancel or refuse to issue, extend or reinstate the Medicaid provider agreement; or

C. Seek denial, suspension or revocation of license granted under Chapter 338, RSMo.

3. The new owner, as a result of a change in ownership, shall have his/her PRA paid by the same method the previous owner elected.

(D) Each pharmacy, upon receiving written notice of the final determination of its PRA, may file a protest with the director of the department setting forth the grounds on which the protest is based, within thirty (30) days from the date of receipt of written notice from the department. The director of the department shall reconsider the determination and, if the pharmacy so requested, grant the pharmacy a hearing to be held within forty-five (45) days after the protest was filed, unless extended by agreement between the pharmacy and the director. The director shall issue a final decision within forty-five (45) days of the completion of the hearing. After a final decision by the director, a pharmacy's appeal of the director's final decision shall be to the Administrative Hearing Commission in accordance with sections 208.156, RSMo 2000 and 621.055, RSMo Supp. 2001.

(E) PRA Rates.

1. The PRA tax rates will be done in bands and will be determined by the ratio of paid Medicaid claims to total prescription sales.

2. The maximum rate shall be six percent (6%).

3. Adjustments will be made to the tax rate if the average Medicaid prescription charge for an individual entity is statistically different than that of the other entities in the assigned tax band.

AUTHORITY: section 208.201, RSMo 2000 and 338.505, RSMo Supp. 2003. Emergency rule filed June 20, 2002, effective July 1, 2002, expired Feb. 27, 2003. Original rule filed July 15, 2002, effective Feb. 28, 2003. Amended: Filed Feb. 3, 2003, effective Aug. 30, 2003. Amended: Filed Nov. 3, 2003, effective April 30, 2004.*

**Original authority: 208.201, RSMo 1987; and 338.505, RSMo 2002.*