
Rules of Department of Social Services

Division 70—Division of Medical Services

Chapter 20—Pharmacy Program

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**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 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 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—

| Drug or Category of Drug | Allowed Indications |
|---|---|
| Amphetamines | Attention Deficit Hyperactivity Disorder Narcolepsy |
| Barbiturates (with the exception of phenobarbital and mephobarbital and methabarbital which do not require prior authorization) | All medically accepted uses |
| Isotretinoin | Noncosmetic uses |
| Orlistat | Dyslipidemia |
| Retinoic Acid, topical | Noncosmetic uses |

AUTHORITY: sections 208.153 and 208.201, RSMo 1994.* 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.

*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—

| Drug or Category | Exceptions—Reimbursable |
|---|---|
| Drugs used to promote fertility | |
| Drugs used to promote weight loss | |
| Drugs used to promote hair growth | |
| Drugs used for cosmetic purposes | |
| Nonlegend vitamins, multivitamins and minerals, adult | Children's Chewable Multi-vitamins Calcium Preparations Iron Preparations |
| Drugs used to promote smoking cessation | |
| Nonlegend lotions, shampoos and medicated soaps | |
| Nonlegend acne preparations | |
| Nonlegend weight control products | |
| Nonlegend ophthalmic products | Artificial tear products Eyewash products Ocular lubricants |
| Contact lens products | |
| Nonlegend oral analgesics | All nonlegend strengths and dosage forms of: Acetaminophen Aspirin Buffered aspirin Ibuprofen Naproxensodium |
| Nonlegend stimulant products | |
| Nonlegend external analgesic products | |

| Drug or Category | Exceptions— Reimbursable |
|---------------------------------|-----------------------------|
| Nonlegend hemorrhoidal products | |
| Halazepam | |
| Prazepam | |
| Estazolam | |
| Quazepam | |

AUTHORITY: sections 208.153 and 208.201, RSMo 1994. Original rule filed Dec. 13, 1991, effective Aug. 6, 1992. Amended: Filed June 30, 2000, effective Feb. 28, 2001.*

**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—

| Drug or Category of Drug | Allowed Indications |
|--|--|
| Abortifacients | Termination of pregnancy resulting from an act of rape or incest or when necessary to protect the life of the mother |
| Butorphanol, nasal spray | Override of quantity restriction allowed for medically accepted uses |
| Drugs used to treat sexual dysfunction | Sexual dysfunction |
| Histamine 2 Receptor Antagonists | Medically accepted uses |
| Ketorolac, oral | Short-term treatment of moderately severe acute pain following injection of same entity |
| Linezolid, oral | Medically accepted uses |
| Modafanil | Narcolepsy |
| Proton Pump Inhibitors | Medically accepted uses |

AUTHORITY: sections 208.152, 208.153 and 208.201, RSMo 1994. Emergency rule filed Nov. 21, 2000, effective Dec. 1, 2000, expired May 29, 2001. Original rule filed June 29, 2000, effective Feb. 28, 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 70-20.040 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 Isoproterenol 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 | Hydralazine | Nitroglycerin Transdermal Systems |
| Codeine Phosphate, Ephedrine Sulfate and Guaifenesin Syrup | Hydralazine and Hydrochlorothiazide | Oxtriphylline |
| Colestipol HCl | Hydralazine, Hydrochlorothiazide and Reserpine | Papaverine HCl Sustained Release 150 mg. |
| Cromolyn Sodium | Hydrochlorothiazide and Lisinopril | Pentoxifylline |
| Demecarium Bromide Ophthalmic Solution | Hydrochlorothiazide and Methyldopa Tablets | Phenobarbital |
| Deserpidine and Methyclothiazide | Hydrochlorothiazide and Metoprolol Tartrate | Phenytoin |
| Dexamethasone Sodium Phosphate Nasal Inhaler | Hydrochlorothiazide and Spironolactone Tablets | Pilocarpine HCl Ophthalmic Solution |
| Dexamethasone Sodium Phosphate Oral Inhaler | Hydrochlorothiazide and Timolol | Pindolol |
| Dichlorophenamide Tablets | Hydrochlorothiazide and Triamterene | Pirbuterol Acetate |
| Dicumarol Tablets | Hydrochlorothiazide Tablets | Polythiazide |
| Diflunisal | Hydrochlorothiazide with Labetalol | Potassium Chloride Capsules |
| Digitalis | Hydroflumethiazide and Reserpine | Potassium Chloride 10% Liquid |
| Digitoxin Tablets | Indapamide Tablets | Potassium Chloride 20% Liquid |
| Digoxin | Indomethacin Suppositories | Potassium Chloride Oral Tablets |
| Diltiazem HCl | Insulin | Potassium Chloride Sustained Release Capsules |
| Diltiazem HCl Sustained Release Capsules | Intravenous Fluids | Potassium Chloride Sustained Release Tablets |
| Dipivefrin HCl Ophthalmic Solution | Dextrose 25%, Sodium Chloride 0.45% | Prazosin HCl |
| Dipyridamole | Dextrose 5% | Primidone |
| Disopyramide | Dextrose 5%, Lactated Ringer's | Probutol |
| Disopyramide Sustained Release Capsules | Dextrose 5%, Sodium Chloride 0.225% | Procainamide HCl Capsules |
| Dyphylline | Dextrose 5%, Sodium Chloride 0.3% | Procyclidine |
| Dyphylline and Guaifenesin | Dextrose 5%, Sodium Chloride 0.45% | Propranolol HCl Sustained Release Capsules |
| Echothiophate Iodide Ophthalmic Solution | Dextrose 5%, Sodium Chloride 0.9% | Propranolol HCl Tablets |
| Enalapril Maleate | Lactated Ringer's | Propylthiouracil |
| Enalapril Maleate and Hydrochlorothiazide | Sodium Chloride 0.45% | Quinethazone Tablets |
| Encainide HCl | Sodium Chloride 0.9% | Quinidine Sulfate Tablets |
| Ephedrine Sulfate Capsules | Ipratropium Bromide | Rauwolfia Serpentina Tablets |
| Ephedrine Sulfate Syrup | Isoetharine HCl | Reserpine and Trichlormethiazide |
| Ephedrine Sulfate and Guaifenesin | Isoflurophate Ophthalmic | Reserpine Tablets |
| Epinephrine Ophthalmic Solution | Isoproterenol | Spironolactone |
| Ergoloid Mesylates Sublingual | Isoproterenol and Phenylephrine Bitartrate Oral Inhaler | Syringes, Disposable, Insulin |
| Ethacrynic Acid | Isosorbide Dinitrate | Terazosin HCl |
| Ethosuximide | Labetalol | Terbutaline Sulfate |
| Flecainide | Levobunolol HCl Ophthalmic Solution | Theophylline |
| Flunisolide Nasal Spray | Levodopa | Theophylline Sustained Release Capsules |
| Flunisolide Oral Inhaler | Levothyroxine Sodium | Theophylline Sustained Release Tablets |
| Furosemide | Lisinopril | Thyroid Tablets |
| Gemfibrozil | Lovastatin | Timolol Maleate |
| Glipizide | Mecamylamine HCl | Tocainide |
| Glyburide | Metaproterenol Sulfate | Tolazamide Tablets |
| Guaifenesin and Oxtriphylline Tablets | Methazolamide Tablets | Tolbutamide |
| Guaifenesin and Phenylpropanolamine HCl Sustained Release Tablets | Methyclothiazide | Triamcinolone Acetonide Oral Inhaler |
| Guaifenesin and Theophylline Sodium Glycinate Tablets | Methyldopa | Trichlormethiazide |
| Guaifenesin and Pseudoephedrine HCl Sustained Release Tablets | Metolazone | Trihexyphenidyl |
| Guaifenesin and Theophylline Capsules | Metoprolol Tartrate | Valproic Acid |
| Guaifenesin and Theophylline Tablets | Metyrosine | Valproic Acid, E.C. |
| Guanabenz Acetate Tablets | Mexiletine HCl | Verapamil HCl |
| Guanadrel Sulfate Tablets | Nadolol Tablets | Verapamil HCl Sustained Release Tablets |
| Guanethidine Monosulfate and Hydrochlorothiazide Tablets | Niacin Tablets | Warfarin Sodium Tablets |
| Guanethidine Monosulfate Tablets | Nicardipine HCl | |
| Guanfacine HCl | Nifedipine Capsules | |
| | Nifedipine Controlled Release Tablets | |
| | Nitroglycerin Spray | |
| | Nitroglycerin Sublingual Tablets | |
| | Nitroglycerin Sustained Release Capsules | |
| | Nitroglycerin Topical Ointment | |

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 L 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 |

AUTHORITY: sections 208.152, 208.153 and 208.201, RSMo 1994. * Emergency rule filed Nov. 21, 2000, effective Dec. 1, 2000, expired May 29, 2001. Original rule filed June 29, 2000, effective Feb. 28, 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 70-20.060 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.

Editor's Note: The secretary of state has determined that the publication of this rule in its entirety would be unduly cumbersome or expensive. The entire text of the material referenced has been filed with the secretary of state. This material may be found at the Office of the Secretary of State or at the headquarters of the agency and is available to any interested person at a cost established by state law.

(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

2. Type of Unit-Dose or Controlled-Dose Drug Distribution System Dispensed in Each Facility

Name

| | |
|-------|-------|
| _____ | _____ |
| _____ | _____ |
| _____ | _____ |
| _____ | _____ |
| _____ | _____ |
| _____ | _____ |
| _____ | _____ |
| _____ | _____ |
| _____ | _____ |
| _____ | _____ |

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.

Editor's Note: The secretary of state has determined that the publication of this rule in its entirety would be unduly cumbersome or expensive. The entire text of the material referenced has been filed with the secretary of state. This material may be found at the Office of the Secretary of State or at the headquarters of the agency and is available to any interested person at a 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 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) 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; or

3. Applicable federal upper limits, as listed in 13 CSR 70-20.071.

AUTHORITY: sections 207.020, RSMo 1986, 208.152, RSMo Supp. 1990, 208.153, RSMo Supp. 1991 and 208.201, RSMo Supp. 1987.* 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.

*Original authority: 207.020, RSMo 1945, amended 1961, 1965, 1977, 1981, 1982, 1986; 208.152, RSMo 1967, amended 1969, 1971, 1972, 1973, 1975, 1977, 1978, 1981, 1986, 1988, 1990; 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

| | | | | | |
|--|--|--|--|------------------|--|
| <input type="checkbox"/> INITIAL REQUEST | | <input type="checkbox"/> RENEWAL REQUEST | | MEDICAID NUMBER | |
| RECIPIENT NAME | | | | DATE OF BIRTH | |
| DIAGNOSIS (TYPE AND SEVERITY; BE VERY SPECIFIC) | | | | | |
| 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 ? <input type="checkbox"/> Yes <input type="checkbox"/> 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)? <input type="checkbox"/> Yes <input type="checkbox"/> 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? <input type="checkbox"/> Yes <input type="checkbox"/> 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.

Editor's Note: The secretary of state has determined that the publication of this rule in its entirety would be unduly cumbersome or expensive. The entire text of the material referenced has been filed with the secretary of state. This material may be found at the Office of the Secretary of State or at the headquarters of the agency and is available to any interested person at a cost established by state law.

(1) 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, except that of the members first appointed, two (2) shall be appointed for one (1) year, two (2) shall be appointed for two (2) years and three (3) shall be appointed for three (3) 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.

(2) All persons eligible for medical assistance benefits shall have access to all pharmaceutical products for which there is federal financial participation except those drugs which 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 which may be restricted and recommend those appropriate for inclusion as a regular benefit of the Missouri Medicaid program or through prior authorization.

(3) 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;

(C) The American Medical Association Drug Evaluations; and

(D) Peer-reviewed medical literature.

(4) If the division finds that the data enumerated in section (3) of this rule has been documented, the Medicaid drug prior authorization committee shall hold a public hearing in order to make recommendations to the department prior to any final decision by the division to require prior authorization for that pharmaceutical product, class or category.

(5) If, after the hearing required pursuant to section (4) of this rule, prior authorization of the pharmaceutical product is required, this prior authorization requirement shall be reviewed at least once every twelve (12) months by the Medicaid drug prior authorization committee.

(6) The division shall not otherwise restrict the prescribing and dispensing of covered outpatient prescription drugs (other than Drug Efficacy Implementation Study (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.

(7) 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*).

AUTHORITY: sections 208.153, RSMo Supp. 1991 and 208.201, RSMo Supp. 1987.* Original rule filed Feb. 3, 1992, effective Aug. 6, 1992.

*Original authority: 208.153, RSMo 1967, amended, 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 com-

mittee 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 estab-

lished 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 made 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.*