### 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.


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(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.

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—

<table>
<thead>
<tr>
<th>Drug or Category of Drug</th>
<th>Allowed Indications</th>
<th>Exceptions—Reimbursable</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amphetamines</td>
<td>Attention Deficit</td>
<td>Children’s Chewable Multivitamins</td>
</tr>
<tr>
<td></td>
<td>Hyperactivity Disorder</td>
<td>Calcium Preparations</td>
</tr>
<tr>
<td></td>
<td>Narcolepsy</td>
<td>Iron Preparations</td>
</tr>
<tr>
<td>Barbiturates (with the</td>
<td>All medically accepted uses</td>
<td></td>
</tr>
<tr>
<td>exception of phenobarbital</td>
<td></td>
<td></td>
</tr>
<tr>
<td>and mephobarbital which</td>
<td></td>
<td></td>
</tr>
<tr>
<td>do not require prior</td>
<td></td>
<td></td>
</tr>
<tr>
<td>authorization)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Isotretinoin</td>
<td>Noncosmetic uses</td>
<td></td>
</tr>
<tr>
<td>Orlistat</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Retinoic Acid, topical</td>
<td>Noncosmetic uses</td>
<td></td>
</tr>
</tbody>
</table>


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)(2), 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—

<table>
<thead>
<tr>
<th>Drug or Category of Drug</th>
<th>Conditions</th>
<th>Exceptions—Reimbursable</th>
</tr>
</thead>
<tbody>
<tr>
<td>Drugs used to promote</td>
<td>Noneligible</td>
<td>Children’s Chewable Multi-vitamins</td>
</tr>
<tr>
<td>fertility</td>
<td></td>
<td>Calcium Preparations</td>
</tr>
<tr>
<td>Drugs used to promote</td>
<td>Noneligible</td>
<td>Iron Preparations</td>
</tr>
<tr>
<td>weight loss</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Drugs used to promote</td>
<td>Noneligible</td>
<td></td>
</tr>
<tr>
<td>hair growth</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Drugs used for cosmetic</td>
<td>Noneligible</td>
<td></td>
</tr>
<tr>
<td>purposes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nonlegend vitamins, multi-vitamins and minerals, adult</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nonlegend external</td>
<td>Noneligible</td>
<td>Artificial tear products</td>
</tr>
<tr>
<td>analgesic products</td>
<td></td>
<td>Eyewash products</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Ocular lubricants</td>
</tr>
<tr>
<td></td>
<td></td>
<td>All nonlegend strengths and dosage forms of:</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Acetaminophen</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Aspirin</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Buffered aspirin</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Ibuprofen</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Naproxensodium</td>
</tr>
</tbody>
</table>

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.


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—

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


Clonidine Transdermal Systems
Codeine Phosphate, Ephedrine Sulfate and Guaifenesin Syrup
Colestipol HCl
Cromolyn Sodium
Demecarium Bromide Ophthalmic Solution
Deserpidine and Methylclothiazide
dexamethasone Sodium Phosphate
Nasal Inhaler
Dexamethasone Sodium Phosphate Oral Inhaler
Dichlorphenamide Tablets
Dicumarol Tablets
Diflunisal
Digitalis
Digitoxin Tablets
Diltiazem HCl
Diltiazem HCl Sustained Release Capsules
Dipivefrin HCl Ophthalmic Solution
Dipyridamole
Disopyramide
Disopyramide Sustained Release Capsules
Dyphylline
Dyphylline and Guaifenesin
Echotoephate 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
Glibizide
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
Guancacenic HCl
Hydralazine
Hydralazine and Hydrochlorothiazide
Hydralazine, Hydrochlorothiazide and Reserpine
Hydrochlorothiazide and Lisinopril
Hydrochlorothiazide and Methyl dopa 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
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
Methylclothiazide
Methyldopa
Metolazone
Metoprolol Tartrate
Metyrosine
Mexiletine HCl
Nadolol Tablets
Niacin Tablets
Nicardpine HCl
Nifedipine Capsules
Nifedipine Controlled Release Tablets
Nitroglycerin Spray
Nitroglycerin Sublingual Tablets
Nitroglycerin Sustained Release Capsules
Nitroglycerin Topical Ointment
Nitroglycerin Transdermal Systems
Oxtriphyllyne
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
Prasozin HCl
Primidone
Procainamide HCl Capsules
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
Terasosin HCl
Terbutaline Sulfate
Theophylline
Theophylline Sustained Release Capsules
Theophylline Sustained Release Tablets
Thyroid Tablets
Timolol Maleate
Tocaoinde
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

Medication may be dispensed in quantities under the provisions of this rule. In addition to the thirty-one (31) day supply limitation, which may be provided per dispensing on pharmacy services, there are special provisions for certain medications:

1. **Controlled-dose delivery system.** A pharmacy must use a controlled-dose delivery system for certain medications, including:
   - Contraceptives, Oral
   - Drug products limited by packaging requirements
   - Vitamins, Children's
   - Vitamins, Prenatal

2. **Effortless dispensing.** Antiretroviral agents are exempt from the thirty-one (31) day supply limitation and may be provided individually wrapped, or in blister cards, all of which must be dispensed according to applicable state and federal laws or regulations.

PURPOSE: The Division of Medical Services shall not pay for an unused pharmacy item returned to the dispensing pharmacy by 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.

When a pharmacy dispenses drugs in a controlled-dose delivery system, the pharmacy must give the Division of Medical Services a credit for all reusable items (any unused portion not taken by the Medicaid recipient) returned to the dispensing pharmacy by or on behalf of a Medicaid recipient.

**3.050 Return of Drugs**

PURPOSE: The Division of Medical Services shall establish that when a pharmacy dispenses drugs in a controlled-dose delivery system, the pharmacy must provide 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:
   - Controlled-dose delivery system: A system of dispensing medications on pharmacy services that is designed to minimize dispensing errors and maximize the efficiency of pharmacy operations.

13 CSR 70-20.050 Return of Drugs

*Original authority: 208.201, RSMo 2000.*

**30.060 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, raising the current dispensing fee from two dollars seventy-five

*Original authority: 208.201, RSMo 1987.*
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.


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
   __________________________________________________________
   __________________________________________________________
   __________________________________________________________
   __________________________________________________________
   __________________________________________________________
   __________________________________________________________
   __________________________________________________________
   __________________________________________________________
   __________________________________________________________
   __________________________________________________________
   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 ______________

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

   __________________________________________________________
   __________________________________________________________
   __________________________________________________________
   __________________________________________________________
   __________________________________________________________
   __________________________________________________________
   __________________________________________________________
   __________________________________________________________
   __________________________________________________________
   __________________________________________________________

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 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%).


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.


## Chapter 20—Pharmacy Program

### 13 CSR 70-20

<table>
<thead>
<tr>
<th>INITIAL REQUEST</th>
<th>RENEWAL REQUEST</th>
<th>MEDICAID NUMBER</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**RECIPIENT NAME**

**DATE OF BIRTH**

**DIAGNOSIS (TYPE AND SEVERITY, SEVERITY 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?

- [ ] 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

**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 885-3003 (3/93)
13 CSR 70-20.080 Labeling of Medicaid Prescriptions
(Rescinded December 9, 1993)


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


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


13 CSR 70-20.120 Medicaid Program Coverage of Anti-Ulcer Preparations
(Rescinded 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.

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) 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, to practice 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 and recommended by the Division of Medical Services out of appropriations made for that purpose.

(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 predetermine 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).

(8) When implementing the provisions of section (3), 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,
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 decision 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.


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, Kirkville 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.


(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;

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.
(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 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 purposes 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.
