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

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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.

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) 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 an 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 *** emergency room visits.
*(F) Nursing facility services.
*(G) Other laboratory and X-ray services.
*(H) Renal dialysis.

Such term also does not include any such drug or product which is used for a medical indication which is not a medically 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.

13 CSR 70-20-031 List of Restricted 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 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>Amphetamines</td>
<td>Attention Deficit Hyperactivity Disorder, Narcolepsy</td>
</tr>
<tr>
<td>Barbiturates (with the exception of phenobarbital and mephobarbital which do not require prior authorization)</td>
<td>All medically accepted uses, Noncosmetic uses, Short-term treatment of moderately severe acute pain following injection of same entity, Noncosmetic uses, Erectile dysfunction</td>
</tr>
<tr>
<td>Isotretinoin</td>
<td></td>
</tr>
<tr>
<td>Ketoralac, oral</td>
<td></td>
</tr>
<tr>
<td>Retinoic Acid, topical</td>
<td></td>
</tr>
<tr>
<td>Sildenafil Citrate</td>
<td></td>
</tr>
</tbody>
</table>

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


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—

<table>
<thead>
<tr>
<th>Drug or Category (Reimbursable)</th>
<th>Exceptions (Reimbursable)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Drugs used to promote fertility</td>
<td>Children’s Chewable Multi-vitamins</td>
</tr>
<tr>
<td>Drugs used to promote weight loss</td>
<td>Calcium Preparations</td>
</tr>
<tr>
<td>Drugs used to promote hair growth</td>
<td>Iron Preparations</td>
</tr>
<tr>
<td>Drugs used for cosmetic purposes</td>
<td>Drugs used to promote smoking cessation</td>
</tr>
<tr>
<td>Nonlegend vitamins, multivitamins and minerals, adult</td>
<td>Nonlegend lotions, shampoos and medicated soaps</td>
</tr>
<tr>
<td>Nonlegend acne preparations</td>
<td>Nonlegend weight control products</td>
</tr>
<tr>
<td>Nonlegend ophthalmic products</td>
<td>Artificial tear products</td>
</tr>
<tr>
<td>Ocular lubricants</td>
<td>Eyewash products</td>
</tr>
<tr>
<td>Contact lens products</td>
<td>All nonlegend strengths and dosage forms of:</td>
</tr>
<tr>
<td>Nonlegend oral analgesics</td>
<td></td>
</tr>
</tbody>
</table>
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.

Acetabutol HCl
Acetazolamide
Acetohexamide
Albuterol
Albuterol Sustained Release Tablets
Amanadine HCl
Amiloride HCl and Hydrochlorothiazide Tablets
Amiloride HCl Tablets
Aminophylline
Anhydrous Calcium Iodide and Isoproteral Sulfate Syrup
Atenolol and Chlorthalidone Tablets
Atenolol Tablets
Beclomethasone Dipropionate
Bendroflumethiazide
Bendroflumethiazide and Nadolol Tablets
Benztropine Mesylate
Betaxolol HCl Ophthalmic Solution
Betheane HCl Chloride
Biperiden Tablets
Bitolterol Mesylate
Bumetanide Tablets
Captopril and Hydrochlorothiazide Tablets
Captopril Tablets
Carbachol Ophthalmic Solution
Carbamazepine
Carbidopa and Levodopa
Chlorthalidone Tablets
Cholestyramine
Clobibrate
Clonazepam
Clonidine HCl
Clonidine Transdermal Systems
Cone Phosphate, Ephephrine Sulfate and Guaifenesin Syrup
Colestipol HCl
Cromolyn Sodium
Demecarium Bromide Ophthalmic Solution
Dexeridine and Methylcystethionide
Dexamethasone Sodium Phosphate
Nusal Inhaler
Dexamethasone Sodium Phosphate Oral Inhaler
Dichlorphenamine Tablets
Dicumarol Tablets
Diflunisal
Ditigul
Digoxin
Diltiazem HCI
Diltiazem HCI Sustained Release Capsules
Dipivofrin HCl Ophthalmic Solution
Dipryridamole
Disopyramide
Disopryamide Sustained Release Capsules
Dyphylline
Dyphylidine and Guaifenesin
Ecothiophate Iodide Ophthalmic Solution
Enalapril Maleate
Enalapril Maleate and Hydrochlorothiazide
Encainide HCl
Ephedrine Sulfate Capsules
Ephedrine Sulfate Sypur
Ephedrine Sulfate and Guaifenesin
Epinephrine Ophthalmic Solution
Ergoloid Mesylates Sblungula
Ethacrynic Acid
Ethosuximide
Flecainide
Flunisolide Nasal Spray
Flunisolide Oral Inhaler
Furosemide
Gemfibrozil
Glipizide
Glyburide
Guaifenesin and Oxtipryline Tablets
Guaifenesin and Phenylpropanolamine
HCl Sustained Release Tablets
Guaifenesin and Theophylline Sodium Glycinate Tablets
Guaifenesin and Pseudoephedrine HCl Sustained Release Tablets
Guaifenesin and Theophylline Capsules
Guaifenesin and Theophylline Tablets
Guanabenz Acetate Tablets

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.

Rebecca McDowell Cook
Secretary of State

Code of State Regulations

13 CSR 70-20—SociAl Services

Division 70—Division of Medical Services

Guanadrel Sulfate Tablets
Guanethidine Monosulfate and Hydrochlorothiazide Tablets
Guanethidine Monosulfate Tablets
Guancine HCl
Hydralazine
Hydralazine and Hydrochlorothiazide
Hydralazine, Hydrochlorothiazide and Reserpine
Hydrochlorothiazide and Lisinopril
Hydrochlorothiazide and Methyldopa Tablets
Hydrochlorothiazide and Metoprolol Tartrate
Hydrochlorothiazide and Spironolactone Tablets
Hydrochlorothiazide and Timolol
Hydrochlorothiazide and Triamterene
Hydrochlorothiazide Tablets
Hydrochlorothiazide with Labetalol
Hydroflumethiazide and Reserpine
Hydrochlorothiazide and Labetalol
Hydrochlorothiazide and Triamterene
Hydrochlorothiazide and Spironolactone
Hydrochlorothiazide and Methyldopa
Hydrochlorothiazide and Metoprolol
Therapeutically inactivated

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
Isolufatophate Ophthalmic
Isoproterenol
Isoproterenol and Phenylephrine
Bitartrate Oral Inhaler
Isosorbide Dinitrate
Labetalol
Levobunolol HCl Ophthalmic Solution
Levodopa
Levophylaxine Sodium
Lisinopril
Lovastatin
Mecamylamine HCl
Metaproterenol Sulfate
Methazolamide Tablets
Methyclothiazide
Methyldopa
Metolazone
Metoprolol Tartrate
Metoxorexine
Mexiletine HCl
Nadolol Tablets
Niacin Tablets
Nicardipine HCl
Nifedipine Capsules
Nifedipine Controlled Release Tablets
Nitroglycerin Spray
Nitroglycerin Sublingual Tablets
Nitroglycerin Sustained Release Capsules
Nitroglycerin Topical Ointment
Nitroglycerin Transdermal Systems
Oxtiophylline
Papaverine HCl Sustained Release 150 mg.
Penitoxifylline
Phenobarbital
Phenytoin
Pilocarpine HCl Ophthalmic Solution
Pindolol
Pibuterol Acetate
Polythiazide
Potassium Chloride Capsules
Potassium Chloride 10% Liquid
Potassium Chloride 20% Liquid
Potassium Chloride Oral Tablets
Potassium Chloride Sustained Release Capsules
Potassium Chloride Sustained Release Tablets
Prazosin HCl
Primidone
Probufol
Procainamide HCl Capsules
Procyclidine
Propranolol HCl Sustained Release
Procyclidine
Propylthiouracil
Propranolol HCl Tablets
Propylthiouracil
Quinethazone Tablets
Quinidine Sulfate Tablets
Rauwolfa Serpentina Tablets
Reserpine and Trichlormethiazide
Reserpine Tablets
Spironolactone
Syringes, Disposable, Insulin
Terazosin HCl
Terbutaline Sulfate
Theophylline
Theophylline Sustained Release Capsules
Theophylline Sustained Release Tablets
Thyroid Tablets
Timolol Maleate
Toctainide
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

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.


MISSOURI MEDICAID
LONG TERM CARE PHARMACY DISPENSING FEE
PROVIDER SPECIALTY APPLICATION

PROVIDER INFORMATION

Complete or affix provider label below:
Missouri Medicaid Provider Number ______________________
Provider Name ______________________
Provider Address ______________________

Business telephone ___(____)________

APPLICATION

1. Facilities For Whom You Dispense in Unit-Dose or Controlled-Dose Drug Distribution System
   Drug Distribution System
   Name __________________________________________
   __________________________________________
   __________________________________________
   __________________________________________
   __________________________________________
   __________________________________________
   __________________________________________

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

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

_________________________  ______________________
Provider Signature        Date

Return to: Provider Enrollment Unit
           Division of Medical Services
           P.O. Box 6500
           Jefferson City, MO 65102-6500
           Telephone No: (314)751-2617
Chapter 20—Pharmacy Program

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.


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.


MISSOURI DEPARTMENT OF SOCIAL SERVICES
DIVISION OF MEDICAL SERVICES

DRUG PRIOR AUTHORIZATION

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

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

[ ] INITIAL REQUEST  [ ] RENEWAL REQUEST

RECIPIENT NAME  MEDICAID NUMBER

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?  [ ] Yes  [ ] No

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

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

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

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

For request for reimbursement for brand name drug: Was generic of requested drug tried?  [ ] Yes  [ ] No

If yes, state results:

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

REQUESTING PHYSICIAN NAME  TELEPHONE NUMBER

ADDRESS

PHYSICIAN'S SIGNATURE  PROVIDER NUMBER

MO 886-3003 (3-93)
13 CSR 70-20.080 Labeling of Medicaid Prescriptions
(Rescinded December 9, 1993)


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.

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. 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 Pharmacopeia 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).


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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(A) Establishing eligibility;
(B) Determining the amount of medical assistance;
(C) Providing services for recipients; and
(D) Conducting or assisting an investigation, prosecution, or civil or criminal proceeding related to the administration of the program.

(14) Provider Responsibility Regarding Confidentiality of Information. All information concerning applicants and recipients of medical services shall be confidential. Any disclosure of 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.

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 Medicare 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
   
   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 Drug Interactions;
   
   C. Side Effects.
      1. Additive toxicity side effects.
      2. Medical condition/additive side effect.
      3. Side effect.
      4. Drug indicated for side effect of previously prescribed drug;
   
   D. Dose Range Checking.
      1. High dose alert.
      2. Low dose alert;
   
   E. Minimum/Maximum Daily Dose.
      1. High dose alert.
      2. Low dose alert;
   
   F. Duplicate Therapy Checking.
      1. Therapeutic duplication.
      2. Ingredient duplication; and
   
   G. Duration of Therapy (H2).
      1. Excessive duration alert.

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

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

   A. The name, address, telephone number, date of birth (or age) and gender of the patient;
   
   B. Individual medical history, if significant, including disease states, known allergies and drug reactions, and a comprehensive list of medications and relevant devices; and
   
   C. Pharmacist’s comments relevant to the individual’s drug therapy.

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

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

   A. Establishing eligibility;
   
   B. Determining the amount of medical assistance;
   
   C. Providing services for recipients; and
   
   D. Conducting or assisting an investigation, prosecution, or civil or criminal proceeding related to the administration of the program.

(9) Provider Responsibility Regarding Confidentiality of Medicaid Beneficiary Information. All information concerning applicants and recipients of medical services shall be confidential. Any disclosure of this information by the pharmacy provider shall be restricted to purpose directly related to the treatment of the patient and promotion of improved quality of care, or conducting or assisting an investigation, prosecution, or civil or criminal proceeding related to the administration of the program. The confidential information includes:
(A) Names and addresses;
(B) Social Security number;
(C) Medical services provided;
(D) Social and economic conditions or circumstances;
(E) Medical data, including diagnosis and past history of disease or disability;
(F) Any information received for verifying income eligibility; and
(G) Any information received in connection with the identification of legally liable third party resources.
