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Missouri



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Documents will be accepted for filing on all regular workdays from 8:00 a.m. until 5:00 p.m. We encourage early filings to facilitate the timely publication of the *Missouri Register*. Orders of Rulemaking appearing in the *Missouri Register* will be published in the *Code of State Regulations* and become effective as listed in the chart above. Advance notice of large volume filings will facilitate their timely publication. We reserve the right to change the schedule due to special circumstances. Please check the latest publication to verify that no changes have been made in this schedule. To review the entire year's schedule, please check out the web site at http://www.sos.state.mo.us/adrules/pubsched.asp

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HOW TO CITE RULES AND RSMo

RULES—Cite material in the *Missouri Register* by volume and page number, for example, Vol. 26, *Missouri Register*, page 27. The approved short form of citation is 26 MoReg 27.

The rules are codified in the Code of State Regulations in this system—

TitleCode of State RegulationsDivisionChapterRule1CSR10-1.010DepartmentAgency, DivisionGeneral area regulatedSpecific area regulated

They are properly cited by using the full citation, i.e., 1 CSR 10-1.010.

Each department of state government is assigned a title. Each agency or division in the department is assigned a division number. The agency then groups its rules into general subject matter areas called chapters and specific areas called rules. Within a rule, the first breakdown is called a section and is designated as (1). Subsection is (A) with further breakdown into paragraph 1., subparagraph A., part (I), subpart (a), item I. and subitem a.

RSMo—Cite material in the RSMo by date of legislative action. The note in parentheses gives the original and amended legislative history. The Office of the Revisor of Statutes recognizes that this practice gives users a concise legislative history.

ules appearing under this heading are filed under the authority granted by section 536.025, RSMo 2000. An emergency rule may be adopted by an agency if the agency finds that an immediate danger to the public health, safety or welfare, or a compelling governmental interest requires emergency action; follows procedures best calculated to assure fairness to all interested persons and parties under the circumstances; follows procedures which comply with the protections extended by the Missouri and the United States Constitutions; limits the scope of such rule to the circumstances creating an emergency and requiring emergency procedure, and at the time of or prior to the adoption of such rule files with the secretary of state the text of the rule together with the specific facts, reasons and findings which support its conclusion that there is an immediate danger to the public health, safety or welfare which can be met only through the adoption of such rule and its reasons for concluding that the procedure employed is fair to all interested persons and parties under the circumstances.

as may be effective not less than ten (10) days after filing or at such later date as may be specified in the rule and may be terminated at any time by the state agency by filing an order with the secretary of state fixing the date of such termination, which order shall be published by the secretary of state in the *Missouri Register* as soon as practicable.

Il emergency rules must state the period during which they are in effect, and in no case can they be in effect more than one hundred eighty (180) calendar days or thirty (30) legislative days, whichever period is longer. Emergency rules are not renewable, although an agency may at any time adopt an identical rule under the normal rulemaking procedures.

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

EMERGENCY AMENDMENT

13 CSR 70-20.200 Drug Prior Authorization Process. The division is amending this rule by adding section (8).

PURPOSE: The purpose of this rule is to clarify the process by which existing drugs included in the Medical Assistance Program may be restricted.

EMERGENCY STATEMENT: Cost Containment through prior authorization of additional drugs was identified in the State Fiscal Year (SFY) 2002 budget in the amount of \$4.9 million annually. During SFY 2002, the division attempted to implement prior authorization of certain drugs to achieve the pharmacy cost containment's identified through that budgetary process. These attempts met with opposition due to differences in interpretation of 13 CSR 70-20.200(3). The division committed to withdraw the proposed rules and take steps to clarify the language. This amendment provides the clarification of the terms in controversy. Expansion of prior authorization of drugs in medical assistance programs has been recognized as a prudent cost containment measure across the country. The SFY 2002 revenue projection is expected to be about

\$750 million less than the original consensus revenue forecast. This forecast was arrived at in December 2000 and provides the basis for the SFY 2002 budget established by the legislature and signed by the Governor. For SFY 2003, the state is projecting general revenue will be \$56 million less than actual net collections in SFY 2001. This does not take into account the impact of inflation. Assuming this projection is accurate, the state will have less money to operate than two years ago while it must fund mandatory items such as Medicaid caseload growth. The state fiscal situation presents an emergency in that it is necessary to take steps to implement pharmacy cost containment measures in order to preserve the compelling governmental interest of reducing expenditures to meet revenues and balance the state budget. This must be accomplished in such a way as to clarify those issues in controversy so the cost containment measures can proceed without further hindrance. The scope of this emergency amendment is limited to the circumstances creating the emergency and complies with the protections extended in the Missouri and United States Constitutions. The Division of Medical Services believes this emergency amendment is fair to all interested persons and parties under the circumstances. This emergency amendment was filed May 22, 2002, effective June 1, 2002 and expires November 27, 2002.

(8) When implementing the provisions of section (3), Missourispecific data shall include the consideration of use and cost data, pharmacoeconomic information and prudent utilization of state funds, and may include medical and clinical criteria.

AUTHORITY: sections 208.153[, RSMo Supp. 1991] and 208.201, RSMo [Supp. 1987] 2000. Original rule filed Feb. 3, 1992, effective Aug. 6, 1992. Emergency amendment filed May 22, 2002, effective June 1, 2002, expires Nov. 27, 2002.

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

EMERGENCY RULE

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

PURPOSE: The purpose of this rule is to outline 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.

EMERGENCY STATEMENT: Expansion of prior authorization of drugs in medical assistance programs across the country has been recognized as a prudent cost containment measure. Missouri's economic status calls for emergency measures to contain cost wherever feasible. The State Fiscal Year (SFY) 2002 revenue projection is expected to be \$750 million less than the original consensus revenue forecast, which was established in December 2000. The Department of Social Services has been required to withhold funds appropriated in the SFY 2002 budget in response to the shortfall in projected revenues in August 2001, December 2001, and May 2002. These withholdings have totaled \$53.4 million in General Revenue funds and \$24.3 million in other state funds. For SFY 2003, the state is projecting general revenue will be \$56 million less than actual net collections in SFY 2001. This does not take into account the impact of inflation. Assuming this projection is accurate, the state will have less money to operate than two years ago while it must fund mandatory items such as Medicaid caseload growth. In the SFY 2003 budget, the Department of Social Services' appropriation indicates cost containment in pharmacy costs in the Medical Assistance Program of over \$100 million (state and federal funds), including \$35.5 million in savings through the prior authorization of new drugs. Achieving cost containment necessary through prior authorization requires an effective date for this rule in advance of that which can be obtained through the regular rulemaking process. Promulgation of this emergency rule is necessary to preserve the compelling governmental interest of maximizing pharmacy cost containment to reduce expenditures to match projected actual revenues in SFY 2002 and to achieve a balanced state budget for SFY 2003. The scope of this emergency rule is limited to the circumstances creating the emergency and complies with the protections extended in the Missouri and United States Constitutions. The division believes this emergency rule is fair to all interested persons and parties under the circumstances. This emergency rule was filed May 22, 2002, effective June 1, 2002 and expires November 27, 2002.

- (1) New drug entities, and new drug product dosage forms of existing drug entities, that have been approved by the Food and Drug Administration and are available on the market, shall comply with prior authorization requirements imposed by the division, in compliance with federal law.
- (2) Prior authorization restrictions shall continue on new drug entities and new drug product dosage forms of existing drugs until reviewed by the division and the division eliminates the restriction or makes a final determination to require restriction. The division shall consider known cost and use data, medical and clinical criteria, and prudent utilization of state funds in the review. Interested parties may present clinical data to the division.
- (3) The review referenced in (2) shall occur within 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 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. Staff recommendations regarding continued prior authorization of a new drug or new drug dosage form shall be made in writing to the MDPAC. 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 15 minutes for interested parties 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 (5) above, prior authorization of the new drug or new drug dosage form is required, the prior authorization requirement shall be reviewed at least once every twelve (12) months by the MDPAC.

AUTHORITY: sections 208.153 and 208.201, RSMo 2000. Emergency rule filed May 22, 2002, effective June 1, 2002, expires Nov. 27, 2002.

Title 19—DEPARTMENT OF HEALTH AND SENIOR SERVICES

Division 20—Division of Environmental Health and Communicable Disease Prevention Chapter 26—Sexually Transmitted Diseases

EMERGENCY AMENDMENT

19 CSR 20-26.050 Preventing Transmission of Human Immunodeficiency Virus (HIV) and Hepatitis B Virus (HBV) from Health Care Workers to Patients. The division is deleting section (4).

PURPOSE: This amendment is to remove the sunset clause on this rule in order to continue the established training requirements relating to the prevention of the transmission of the Human Immunodeficiency Virus, Hepatitis B Virus and other bloodborne pathogens from infected health care workers to patients.

EMERGENCY STATEMENT: In 1992, section 191.694, RSMo, was passed requiring that all health care professionals who perform invasive procedures shall receive training on infection control procedures relevant to HIV and related diseases. Currently there is a sunset clause which provides that this rule is due to expire on June 30, 2002. As this rule is necessary for the continued implementation and administration of section 191.694, RSMo, the Missouri Department of Health and Senior Services finds an immediate danger to the public health and welfare and a compelling governmental interest, which requires emergency action to remove this sunset clause. A proposed amendment, which covers the same material, is published in this issue of the Missouri Register. The scope of this rule is limited to the circumstances creating the emergency and complies with the protection extended in the Missouri and the United States Constitutions. The Commission believes this emergency rule is fair to all interested persons and parties under the circumstances. This emergency amendment was filed May 10, 2002, effective July 1, 2002, and expires December 28, 2002.

[(4) This rule expires on June 30, 2002.]

AUTHORITY: section 191.694.4, RSMo 2000. Original rule filed April 17, 1995, effective Nov. 30, 1995. Emergency amendment filed May 10, 2002, effective July 1, 2002, expires Dec. 28, 2002. A proposed rule covering this same material is published in this issue of the Missouri Register.

Title 19—DEPARTMENT OF HEALTH AND SENIOR SERVICES

Division 20—Division of Environmental Health and Communicable Disease Prevention Chapter 26—Sexually Transmitted Diseases

EMERGENCY AMENDMENT

19 CSR 20-26.060 Voluntary Evaluation for the Human Immunodeficiency Virus (HIV)- and Hepatitis B Virus (HBV)-Infected Health Care Professionals Who Perform Invasive Procedures. The division is deleting section (5).

PURPOSE: This amendment is to remove the sunset clause in this rule in order to continue the established procedures for the voluntary evaluation of the Human Immunodeficiency Virus and

Hepatitis B Virus for infected health care professionals who perform invasive procedures in order to determine whether practice restrictions or limitations should be applied.

EMERGENCY STATEMENT: In 1992, section 191.700, RSMo was passed requiring the Department of Health to set an expert review panel to evaluate the Human Immunodeficiency Virus (HIV) and the Hepatitis B Virus infected health care professionals who perform invasive procedures. This evaluation is voluntary on the part of the infected health care professional. Currently, there is a sunset clause which provides that this rule is due to expire on June 30, 2002. As this role is necessary for the continued implementation and administration of section 191.700, RSMo, the Missouri Department of Health and Senior Services finds an immediate danger to the public health and welfare and a compelling governmental interest, which requires emergency action to remove this sunset clause. A proposed amendment, which covers the same material, is published in this issue of the Missouri Register. The scope of this rule is limited to the circumstances creating the emergency and complies with the protection extended in the Missouri and the United States Constitutions. The Commission believes this emergency rule is fair to all interested persons and parties under the circumstances. This emergency amendment was filed May 10, 2002, effective July 1, 2002, expires December 28, 2002.

[(5) This rule expires on June 30, 2002.]

AUTHORITY: section 191.700.2, RSMo 2000. Original rule filed April 17, 1995, effective Nov. 30, 1995. Emergency amendment filed May 10, 2002, effective July 1, 2002, expires Dec. 28, 2002. A proposed rule covering this same material is published in this issue of the Missouri Register.