

Volume 27, Number 5
Pages 383-446
March 1, 2002



Matt Blunt
Secretary of State

MISSOURI REGISTER

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The *Missouri Register* is published semi-monthly by

SECRETARY OF STATE
MAT T BLUNT

Administrative Rules Division
James C. Kirkpatrick State Information Center
600 W. Main
Jefferson City, MO 65101
(573) 751-4015

DIRECTOR

LYNNE C. ANGLE

ADMINISTRATIVE STAFF

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PEGGY TALKEN

EDITORS

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JOHN C. STEGMANN

ISSN 0149-2942, USPS 320-630; periodical postage paid at Jefferson City, MO
Subscription fee: \$56.00 per year

POSTMASTER: Send change of address notices and undelivered copies to:

MISSOURI REGISTER
Office of the Secretary of State
Administrative Rules Division
PO Box 1767
Jefferson City, MO 65102

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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—

Title	Code of State Regulations	Division	Chapter	Rule
1	CSR	10-	1.	010
Department		Agency, Division	General area regulated	Specific 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.



FROM THIS ANGLE

Do you have your manual?

In October of 2001, we totally revised the rulemaking manual, which is the guide to assisting you in the preparation of your administrative rules. This manual is designed to be very user friendly and refers the user to the specific type of rulemaking they desire to file; with step-by-step instructions of the procedural steps you need to perform from format to actual rule packet. If you do not have your copy of the manual, please contact our office to obtain one. Because they were quite costly to produce, we have tried, in most instances, to limit the copies to one per agency — but want to be certain that everyone who needs one has one in their agency. We believe you will find the manual to be a very useful tool.

We need your help!

In the not too distant future, we are considering instituting an e-mail notification service for our subscribers and other interested parties. This service would send e-mail notification of particular types of rule filings on specific subjects when filed with our office. If you would be interested in this type of service, or have suggestions for additional information to be included in the e-mail notification, we need to hear from you. Please e-mail us at rules@sosmail.state.mo.us or call our main number at 573-751-4015. ***We will appreciate your response to this question!***

Suggestion Box

Please remember to use the suggestion box located on the front reception desk in our office. This is for your use in making constructive criticism, compliments and/or suggestions — we need to hear from you in order to serve you better.

Incorporated by Reference Material . . . Updating the Same

If your agency wishes to update your incorporated by reference material that is allowed; however, you must also amend the rule in which the material is incorporated. If you have questions concerning the updating of incorporation by reference material, please call our office.

As always, we are happy to assist you in any manner in order to make the rulemaking process as smooth as possible for your agency.

A handwritten signature in cursive script, appearing to read "Lynne".

Lynne C. Angle,
Director, Administrative Rules Division

Rules 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.

Rules filed as emergency rules 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.

All 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 9—DEPARTMENT OF MENTAL HEALTH
Division 45—Division of Mental Retardation and
Developmental Disabilities
Chapter 5—Standards**

EMERGENCY RULE

9 CSR 45-5.060 Procedures to Obtain Certification

PURPOSE: This rule describes procedures to obtain certification as a provider of residential habilitation, individualized supported living (ISL), supported employment, and day habilitation (on and off site) through the community-based Medicaid Waiver.

EMERGENCY STATEMENT: This emergency rule informs state agencies and the public of changes in procedures to obtain certification as a provider of residential habilitation, individualized supported living, supported employment, and day habilitation (on and off site). This emergency rule is necessary to protect the public health, safety, and welfare, as some agencies are awarded a certificate to provide services to individuals with developmental disabilities while still having deficiencies and not meeting division's certification standards. This emergency rule will assure that all deficiencies cited of a provider during an on-site visit are corrected before a certificate to provide services is awarded. This emergency rule will also establish greater uniformity with the other division of the department regarding procedures to obtain certifi-

cation as a provider of services. Therefore, the Division of Mental Retardation and Developmental Disabilities finds an immediate danger to the public health, safety, and/or welfare and a compelling governmental interest that requires this emergency action. A proposed rule, which covers the same material, is published in this issue of the Missouri Register. 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 of Mental Retardation and Developmental Disabilities believes this emergency rule is fair to all interested persons and parties under the circumstances. This emergency rule was filed February 13, 2002, effective March 1, 2002, and expires August 27, 2002.

(1) Under sections 630.655, 630.010, and 376.779.3 and 4, RSMo, the department is mandated to develop certification standards and to certify an organization's level of service, treatment or rehabilitation as necessary for the organization to operate, receive funds from the department, or participate in a service network authorized by the department and eligible for Medicaid reimbursement. However, certification in itself does not constitute an assurance or guarantee that the department will fund designated services or programs.

(A) A key goal of certification is to enhance the quality of care and services with a focus on the needs and outcomes of persons served.

(B) The primary function of the certification process is assessment of an organization's compliance with standards of care. A further function is to identify and encourage developmental steps toward improved program operations, client satisfaction and positive outcomes.

(C) This rule replaces sections 9 CSR 45-5.010(4) and (5) of the Certification of Medicaid Agencies Serving Persons with Developmental Disabilities.

(2) An organization may request certification by completing an application form, as required by the department for this purpose, and submitting the application form, and other documentation, as may be specified, to the Department of Mental Health, PO Box 687, Jefferson City, MO 65102.

(A) The organization must submit a current written description of those programs and services for which it is seeking certification by the department.

(B) A new applicant shall not use a name which implies a relationship with another organization, government agency or judicial system when a formal organizational relationship does not exist.

(C) Certification fees are not required.

(D) The department will review a completed application within thirty (30) calendar days of receipt to determine whether the applicant organization would be appropriate for certification. The department will notify the organization of its determination.

(E) An organization that wishes to apply for recertification shall submit its application forms to the department at least sixty (60) days before expiration of its existing certificate.

(F) An applicant can withdraw its application at any time during the certification process, unless otherwise required by law.

(3) The department shall conduct a site survey at an organization to assure compliance with certification standards, standards of care and other requirements.

(A) The department shall conduct a comprehensive site survey for the purpose of determining compliance with certification standards and program/service rules, except as stipulated in paragraphs (3)(B)1. through 3.

(B) The department recognizes and deems as certified a provider that has attained full accreditation under standards for Community

Services (community living services for individualized supported living (ISL) and residential habilitation and personal and social services for day habilitation) and for Employment Services (supported employment) from the Commission on Accreditation of Rehabilitation Facilities (CARF) or The Council on Quality and Leadership in Supports for People with Disabilities (The Council). The deemed provider must—

1. Submit to the department a copy of the most recent accreditation survey report and verification of the accreditation time period and dates within thirty (30) days of receipt from the accreditation agency.

2. Notify the department when accreditation surveys are scheduled or when accreditation agency makes complaint investigation visit.

3. Notify the department of any changes in accreditation status during the time period of accreditation and resurvey.

4. Identify the department as a primary stakeholder for contact by the accrediting agency during survey and resurvey data gathering processes.

(4) The department shall provide advance notice and scheduling of routine, planned site surveys.

(A) The department shall notify the applicant and the division's regional centers regarding survey date(s), procedures and a copy of any survey instrument that may be used. Survey procedures will include, but are not limited to, interviews with provider staff, individuals being served and other interested parties; tour and inspection of program sites; review of provider administrative records necessary to verify compliance with requirements; review of personnel records and service documentation; observation of program activities.

(B) The applicant agrees, by act of submitting an application, to allow and assist department representatives in fully and freely conducting these survey procedures and to provide department representatives reasonable and immediate access to premises, individuals, and requested information.

(C) An organization must engage in the certification process in good faith. The organization must provide information and documentation that is accurate, and complete. Failure to participate in good faith, including falsification or fabrication of any information used to determine compliance with requirements, may be grounds to deny issuance of or to revoke certification.

(D) The surveyor(s) shall hold entrance and exit conferences with the organization to discuss survey arrangements and survey findings, respectively. If a surveyor identifies a deficiency that could result in actual jeopardy to the safety, health or welfare of persons served, the surveyor shall not leave the program until an acceptable plan of correction is presented which assures the surveyor that there is no further risk of jeopardy to persons served.

(E) Within thirty (30) calendar days after the exit conference, the department shall provide a written survey report to the provider's director and the division.

1. The report shall note all deficiencies identified during the survey. Every instance in which the certification standards are not met will be cited as a deficiency.

2. The department shall send a notice of deficiency and the report by certified mail, return receipt requested.

3. The provider shall make the report available to the staff and to the public upon request.

(F) Within thirty (30) calendar days of the date that a notice of deficiency and the report is presented by certified mail to the provider, the provider shall submit to the department and regional center a plan of correction.

1. The plan must address each deficiency, specifying the method of correction and the date the correction shall be completed. The provider will work with the regional center to develop a plan of correction. No correction date will exceed one hundred eighty (180) days.

2. Within fifteen (15) calendar days after receiving the plan of correction, the department shall notify the provider and the division of its decision to approve, disapprove, or require revisions of the proposed plan.

3. The surveyor will assure that the plan of correction has been implemented and deficiencies corrected. The department shall determine if it is necessary for the surveyor to make a return visit to the provider based on the criteria of the plan of correction and will notify the division and regional center(s) of revisit.

4. In the event that the provider has not submitted a plan of correction acceptable to the department within sixty (60) days of the original date that written notice of deficiencies was presented by certified mail to the provider, it shall be subject to expiration of certification.

(5) The department may grant certification on a temporary, provisional, conditional, or compliance status. The department will notify the division of any change in the status of a provider.

(A) Temporary status shall be granted to a provider if the survey process has not been completed prior to the expiration of an existing certificate and the applicant is not at fault for failure or delay in completing the survey process.

(B) Provisional status for a period of not exceeding one (1) year shall be granted to a new provider or service, a converted agency or provider, or an existing provider adding a waived service, based on a site review which finds the program in compliance with requirements related to policy and procedure, facility, personnel, and staffing patterns sufficient to begin providing services. The regional center must notify the Licensure and Certification Office as soon as the contract is set up with the provider.

1. In the department's initial determination and granting of provisional certification, the provider shall not be expected to fully comply with those standards which reflect ongoing program activities.

2. The department shall conduct a comprehensive site survey of the provisionally certified provider and shall make further determination of the provider's certification status no sooner than ninety (90) days after the provider begins serving clients nor later than the expiration date of the provisional certificate.

(C) Conditional status shall be granted to a provider following a site survey by the department that determines that there are pervasive and/or significant deficiencies with standards that may affect quality of care to individuals and there is reasonable expectation that the provider can achieve compliance within a stipulated time period. The department shall consider patterns and trends of performance identified during the site survey.

1. The period of conditional status shall not exceed one hundred eighty (180) calendar days. The department may directly monitor progress, may require the provider to submit progress reports, or both.

2. The department shall conduct a further site survey within the one hundred eighty (180)-day period and make a further determination of the provider's compliance with standards.

3. During the period of conditional status, the division may, at its discretion, take actions per sections (10) and (12) of this rule.

(D) Compliance status shall be awarded to a provider for a period of two (2) years following a site survey by the department that determines the provider meets all standards relating to quality of care and the safety, health, rights, and welfare of persons served. If deficiencies are cited during a site survey, any and all such deficiencies must be corrected in accordance with the plan of correction prior to the department awarding compliance status.

(6) The department may investigate any written complaint regarding the operation of a certified or deemed certified program or service. If conditions are found that are not in compliance with applicable certification standards, the department may, at its sole discretion, notify the accrediting organization of any concerns.

(7) The department may conduct a scheduled or unscheduled site survey of a provider at any time to monitor ongoing compliance with the certification standards. If any survey finds conditions that are not in compliance with applicable certification standards, the department may require corrective action steps and may change the provider's certification status consistent with procedures set out in this rule.

(8) The department shall certify only the provider(s) named in the application. The provider(s) may not transfer certification without the written approval of the department.

(A) A certificate is the property of the department and is valid only as long as the provider meets standards of care and other requirements.

(B) The provider shall maintain the certificate issued by the department in a readily available location.

(C) Within seven (7) calendar days of the time a certified provider organization is sold, leased, discontinued, moved to a new location, has a change in its accreditation status, appoints a new director, or changes programs or services offered, the provider shall provide written notice to the department of any such change.

(D) A certified provider that establishes a new program or type of program shall operate that program in accordance with applicable standards. A provisional review, expedited site survey or comprehensive site survey shall be conducted, as determined by the department.

(9) The department may deny issuance of and may revoke certification based on a determination that—

(A) The nature of the deficiencies results in substantial probability of or actual jeopardy to individuals being served;

(B) Serious or repeated incidents of abuse or neglect of individuals being served or violations of rights have occurred;

(C) Fraudulent fiscal practices have transpired or significant and repeated errors in billings to the department have occurred;

(D) Failure to participate in the certification process in good faith, including falsification or fabrication of any information used to determine compliance with requirements;

(E) The nature and extent of deficiencies results in the failure to conform to the certification standards of the program or service being offered; or

(F) Compliance with standards has not been attained by an organization upon expiration of conditional certification.

(10) The department, at its discretion, may—

(A) Place a monitor at a program if there is substantial probability of or actual jeopardy to the safety, health, rights, or welfare of individuals being served.

1. The cost of the monitor shall be charged to the organization at a rate which recoups all reasonable expenses incurred by the department.

2. The department shall remove the monitor when a determination is made that the safety, health, rights, and welfare of individuals being served is no longer at risk.

(B) Take other action to ensure and protect the safety, health or welfare of individuals being served.

(11) An organization which has had certification denied or revoked may appeal to the director of the department within thirty (30) calendar days following notice of the denial or revocation being presented by certified mail to the organization. The director of the department shall conduct a hearing under procedures set out in Chapter 536, RSMo and issue findings of fact, conclusions of law and a decision which shall be final.

(12) The department shall have authority to impose administrative sanctions.

(A) The department may suspend the certification process pending completion of an investigation when an organization that has applied for certification or the staff of that organization is under investigation for fraud, financial abuse, abuse of persons served, revocation of persons' rights without due process, or improper clinical practices.

(B) The department may administratively sanction a certified organization that has been found to have committed fraud, financial abuse, abuse of persons served, or improper clinical practices or that had reason to know its staff were engaged in such practices.

(C) Administrative sanctions include, but are not limited to, suspension of certification, clinical utilization review requirements, clinical audit, suspension of new admissions, denial or revocation of certification, or other actions as determined by the department.

(D) The department shall have the authority to refuse to accept for a period of up to twenty-four (24) months an application for certification from an organization that has had certification denied or revoked or that has been found to have committed fraud, financial abuse or improper clinical practices or whose staff and clinicians were engaged in improper practices.

(E) An organization may appeal these sanctions pursuant to section (11).

(13) An organization may request the department's exceptions committee to waive a requirement for certification if the head of the organization provides evidence that a waiver is in the best interests of the individuals it serves.

(A) A request for a waiver shall be in writing and shall include justification for the request.

(B) The request shall be submitted to Exceptions Committee, Department of Mental Health, PO Box 687, Jefferson City, MO 65102.

(C) The exceptions committee shall hold meetings in accordance with Chapter 610, RSMo and shall respond with a written decision within forty-five (45) calendar days of receiving a request.

(D) The exceptions committee may issue a waiver on a time-limited or other basis.

(E) If a waiver request is denied, the exceptions committee shall give the organization forty-five (45) calendar days to fully comply with the standard, unless a different time period is specified by the committee.

AUTHORITY: sections 630.050 and 630.655, RSMo Supp. 2001. Emergency rule filed Feb. 13, 2002, effective March 1, 2002, expires Aug. 27, 2002. A proposed rule covering this same material is published in this issue of the Missouri Register.

**Title 13—DEPARTMENT OF SOCIAL SERVICES
Division 40—Division of Family Services
Chapter 30—Permanency Planning for Children**

EMERGENCY RULE

13 CSR 40-30.020 Attorney Fees and Guardian *Ad Litem* Fees in Termination of Parental Rights Cases

*PURPOSE: The purpose of this rule is to establish fees for attorneys and guardians **ad litem** who provide services in termination of parental rights cases.*

*EMERGENCY STATEMENT: The division has determined that an emergency rule is necessary to establish fees for attorneys (including guardians **ad litem**) who provide services in termination of parental rights cases. In fulfilling its responsibility and ensuring that children in foster care achieve permanency, the division finds it necessary in certain cases to initiate termination of parental rights (TPR) proceedings in order to free these children up for adoption. Ensuring that adequate representation of the children*

and the parents is provided in these TPR cases is a vital part of this process. The division finds that an immediate danger to the health, safety and welfare to the citizens of Missouri exists inasmuch as there presently is no rule in effect to provide a fair and equitable procedure for the payment of fees to attorneys and guardians *ad litem* to provide essential representation in TPR cases. Having an established procedure for payment of fees in TPR cases will assist all interested parties by assuring that a definite compensation is awarded under the criteria established. The division finds that this emergency rule is necessary to preserve a compelling governmental interest in achieving permanency for children that requires an early effective date and certifies that the reasons supporting this finding are as follows: 1) it will help to promote fiscal responsibility by conserving monetary resources allocated for representation; 2) it will provide necessary guidance to the courts in determining how compensation will be provided; 3) it will enable all attorneys involved in such cases to know what compensation to expect; and 4) it will help ensure that the best interest of the children are protected by enabling attorneys to be provided definite compensation for their services in these cases. Without this emergency rule, there is a danger that compensation to attorneys will be unequal throughout the state and that the rights of all parties, including the best interest of the children, will not be adequately safeguarded through effective representation. A proposed rule, which covers the same material, is published in this issue of the **Missouri Register**. 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 February 14, 2002, effective February 24, 2002, and expires August 22, 2002.

(1) If permanency for the children requires parental rights be terminated to enable children to be permanently placed or adopted, the children's parents shall be provided representation in such cases which shall include counsel, investigative, expert and other services to ensure adequate representation. This includes the appointment of a guardian *ad litem* for the children. Representation shall be provided for financially eligible persons. A person is considered financially eligible when it appears from all of the circumstances of the case including the person's income, the number of individuals dependent on the person for support, and the person's financial assets and liabilities, that the person does not have the means available to obtain counsel and is indigent. The determination of indigency may be made at any time by the Division of Family Services. Upon motion by any party, the court in which the case is pending shall have the authority to determine, based on a finding of indigence, whether the Division of Family Services should pay for counsel for a particular parent. If the court finds the parent is not indigent, the Division of Family Services shall discontinue paying for counsel on behalf of such parent. Counsel furnishing representation under the plan shall be selected from a panel of attorneys designated or approved by the court, or from a bar association or other organization of attorneys willing to furnish representation of parents in termination of parental rights cases. A person for whom counsel is appointed shall be represented at every stage of the proceeding, from his or her initial appearance through appeal, including ancillary matters appropriate to the proceedings. In the interest of justice, one counsel may be substituted for another at any stage of the proceedings.

(2) Payment for attorney representation shall be made as provided below:

(A) Hourly rate. Any attorney shall, at the conclusion of the representation (i.e., the conclusion of trial or at the conclusion of any appeal, or both at the conclusion of trial and at the conclusion of appeal), be compensated at a rate not exceeding seventy-five dollars (\$75) per hour for time expended in court and fifty dollars

(\$50) per hour for time reasonably expended out of court. Attorneys may be reimbursed for expenses reasonably incurred, including the costs of transcripts authorized by the court.

(B) Maximum amounts. The compensation to be paid for representation at trial shall not exceed seven hundred fifty dollars (\$750) for uncontested matters and two thousand five hundred dollars (\$2,500) for contested matters. For representation in an appellate court, the compensation shall not exceed two thousand five hundred dollars (\$2,500) at fifty dollars (\$50) per hour.

(C) Cost of extraordinary expenses. The cost of extraordinary expenses must be approved in advance by the court. Such extraordinary expenses include:

1. Psychiatric/psychological/medical evaluations;
2. Expert witnesses; and
3. Deposition of witnesses.

(D) Waiving maximum amounts. Payment in excess of any maximum amount provided in subsection (2)(B) may be made for extended or complex representation whenever the court in which the representation was rendered certifies that the amount of the excess payment is necessary to provide fair compensation and the payment is approved by the court.

(E) Disclosure of fees. The amounts paid to particular attorneys or groups of attorneys shall be available as public records. However, the identity of parties, including parents, children, foster parents and anyone whose confidentiality is established in Chapter 210 or 211, RSMo, shall not be publicly available.

(F) Filing claims. A separate claim for compensation and reimbursement shall be made to the Division of Family Services for each case. Each claim shall be supported by a sworn written statement specifying the time expended, services rendered, and expenses incurred while the case was pending before the court, and the compensation and reimbursement applied for or received in the same case from any other source. The Division of Family Services may agree to the claim, may negotiate the claim with the applying attorney, or may deny the claim in which case the attorney shall apply to the court to determine the compensation and reimbursement to be paid to the attorney.

(G) New trials. For purposes of compensation and other payments authorized by this section, an order by a trial or appellate court granting a new trial shall be deemed to initiate a new case.

(H) Receipt of other payments. Whenever the Division of Family Services or the court finds that funds are available for payment from or on behalf of a person furnished representation, it may authorize or direct that such funds be paid to the appointed attorney.

(3) Payment for guardian *ad litem*. Children involved in termination of parental rights cases are entitled to a guardian *ad litem*. The fees for the guardian *ad litem* shall be paid in the maximum amount of two thousand five hundred dollars (\$2,500) at fifty dollars (\$50) per hour for out of court services and seventy-five dollars (\$75) per hour for in court services.

AUTHORITY: section 207.020, RSMo 2000. Emergency rule filed Feb. 14, 2002, effective Feb. 24, 2002, expires Aug. 22, 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 25—Division of Administration

Chapter 38—Laboratory Fees

EMERGENCY RULE

19 CSR 25-38.020 Laboratory Fee for Tuberculosis Testing

PURPOSE: This rule establishes a fee for testing specimens for tuberculosis that are submitted to the State Public Health Laboratory.

EMERGENCY STATEMENT: This emergency rule establishes a charge for specimens submitted to the State Public Health Laboratory for tuberculosis testing. This emergency rule is necessary in order to assure that testing for tuberculosis is maintained at the current level at least through this current fiscal year and for the near future. In FY 00 the department spent over \$750,000 to test some 13,600 specimens for TB and fungal diseases. Due to the current budget situation in the state, the department could only identify funding sources for 60 percent of this level of funding. Even after eliminating testing for fungal diseases, which was done effective December 1, 2001, the level of testing supported by the identified source of funds is too low for effective surveillance for new cases of tuberculosis thus endangering public health. Furthermore, under the existing state accounting system, once the identified source of funds are exhausted, the functions they support will cease to be provided. As a result, the DHSS, State Public Health Laboratory finds an immediate danger to the public health, safety and/or welfare and a compelling governmental interest which requires this emergency action. A proposed rule, which covers the same material, is published in this issue of the **Missouri Register**. 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 Department of Health and Senior Services, State Public Health Laboratory believes this emergency rule is fair to all interested persons and parties under the circumstances. This emergency rule was filed February 15, 2002, effective February 26, 2002, and expires August 24, 2002.

(1) A fee of forty-eight dollars (\$48) shall be charged for each clinical specimen submitted to the State Public Health Laboratory for tuberculosis testing. Clinical specimens are raw sputum samples, gastric lavage samples, urine specimens or pleural, spinal, and joint fluids, other exudates or tissue samples.

(2) The Department of Health and Senior Services (DHSS) may waive the fee for testing clinical specimens that are submitted from local public health departments or when the director of DHSS determines the specimens are of critical importance for the protection of the public health and safety.

AUTHORITY: section 701.322, RSMo 2000. Emergency rule filed Feb. 15, 2002, effective Feb. 26, 2002, expires Aug. 24, 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 90—Missouri Senior Rx Program Chapter 3—Manufacturers Rebate Program

EMERGENCY RULE

19 CSR 90-3.010 Manufacturers Rebate Program

PURPOSE: This rule establishes the pharmaceutical manufacturers rebate program as set forth in section 208.565, RSMo.

EMERGENCY STATEMENT: On October 5, 2001, legislation was enacted that established the Missouri Senior Rx Program to help defray the costs of prescription drugs for elderly Missouri residents who meet the statutory and regulatory requirements for participation in the program. The legislation also established the commission for the Missouri Senior Rx Program to govern the operation

of the Missouri Senior Rx Program. In relevant part, the commission was charged with rulemaking authority for the implementation and administration of the program. The legislation contains a section that provides “[b]ecause immediate action is necessary to ensure the timely provision of prescription drugs to the elderly” the sections applicable to the Missouri Senior Rx Program are “deemed necessary for the immediate preservation of the public health, welfare, peace, and safety, and is hereby declared to be an emergency act within the meaning of the constitution” and as such these sections “shall be in full force and effect upon its passage and approval.” Section 208.559, RSMo, provides that the program shall be operational no later than July 1, 2002. This section continues by providing that program “shall accept applications for enrollment during an initial open enrollment period from April 1, 2002, through May 30, 2002.” Therefore, as this rule is necessary for implementation and administration of the Missouri Senior Rx Program, the Missouri Senior Rx Commission finds an immediate danger to the public health and welfare and a compelling governmental interest, which requires emergency action. The scope of this rule is limited to the circumstances creating the emergency and complies with the protections extended in the **Missouri and United States Constitutions**. The commission believes this emergency rule is fair to all interested persons and parties under the circumstances. The emergency rule was filed February 15, 2002, effective March 1, 2002, and expires August 27, 2002.

(1) Definitions.

(A) The terms defined in this section will, for the purposes of this section, have the meanings specified in section 1927 of the Social Security Act (42 U.S.C., 1396) as interpreted and applied herein:

1. Average manufacturer price (AMP) is, with respect to a covered outpatient drug of the manufacturer for a calendar quarter, the average unit price paid to the manufacturer for the drug in the states by wholesalers for drugs distributed to the retail pharmacy class of trade (excluding direct sales to hospitals, health maintenance organizations and to wholesalers where the drug is relabeled under that distributor’s National Drug Code (NDC) number). Federal Supply Schedule prices are not included in the calculation of AMP to the extent and for the time periods authorized under section 1927 of the Social Security Act. AMP includes cash discounts allowed and all other price reductions (other than rebates under section 1927 of the Social Security Act) which reduce the actual price paid. It is calculated as a weighted average of prices for all the manufacturer’s package size for each covered outpatient drug sold by the manufacturer during that quarter. Specifically, it is calculated as net sales divided by numbers of units sold, excluding free goods (i.e., drugs or any other items given away, but not contingent on any purchase requirements). For bundled sales, the allocation of the discount is made proportionately to the dollar value of the units of each drug sold under the bundled arrangement. The manufacturer must adjust the AMP for a quarter if cumulative discounts or other arrangements subsequently adjust the prices actually realized;

2. Bundled sale refers to the packaging of drugs of different types where the condition of rebate or discount is that more than one drug type is purchased, or where the resulting discount or rebate is greater than that which would have been received had the drug products been purchased separately;

3. Certificate of participation is the application the manufacturer must complete and sign along with the commission to participate in the Missouri Senior Rx Program with an implementation date of July 1, 2002. This executed document will permit the manufacturer’s drugs to be dispensed under the Missouri Senior Rx Program;

4. Department of Health and Senior Services (DHSS) is the state agency that administers the Missouri Senior Rx Program pursuant to the commission’s authority in section 208.556, RSMo;

5. Division of Medical Services (DMS) is the state agency designated by the commission to administer the rebate process for the Missouri Senior Rx Program pursuant to section 208.565, RSMo.

6. Net sales are quarterly gross sales revenue less cash discounts allowed and all other price reductions (other than rebates under section 1927 of the Social Security Act) which reduce the actual price paid; and as further defined under the definition of AMP;

7. Quarter is a calendar quarter unless otherwise specified;

8. Rebate payment is, with respect to the manufacturer's covered outpatient drugs, the quarterly payment by the manufacturer to the Missouri Senior Rx Program, which shall be the sum of the unit rebate amount (URA) of each drug product (computed for each dosage form the strength of each covered outpatient drug) calculated as follows:

A. The total number of units dispensed under the Missouri Senior Rx Program for the program participants during the quarter multiplied by unit rebate amount for the drug, $(AMP \times .15)$;

9. State is the state of Missouri;

10. Unit rebate amount (URA) is the unit amount computed by the manufacturer to which the Missouri Senior Rx Program utilization information may be applied by the Missouri Senior Rx Program in invoicing the manufacturer for the rebate payment due. The amount of the rebate will be computed in accordance with and will conform to section 208.565.2, RSMo at fifteen percent (15%) of AMP; and

11. Missouri Senior Rx Utilization Information is the information on the total number of units of each dosage form and strength of the manufacturer's covered outpatient drugs for which claims were approved and processed during a quarter under the Missouri Senior Rx Program. This information is based on claims approved and processed by the Missouri Senior Rx Program during a calendar quarter and not drugs that were dispensed during a calendar quarter. Missouri Senior Rx Program utilization information will include at a minimum for each product code, using the 11-digit NDC number, package size and product name, the total number of claims (number of scripts), total allowed charges and total units dispensed. The Missouri Senior Rx Program may, at its option, compute the total rebate anticipated, based on pricing data received from the manufacturer, but it shall remain the responsibility of the manufacturer to correctly calculate the rebate amount.

(2) Manufacturer's Responsibilities.

(A) In order for the Missouri Senior Rx Program to authorize payments for the manufacturer's covered outpatient drugs for program participants in accordance with section 208.556, RSMo the manufacturer must complete a Certificate of Participation and agree to the following:

1. Thirty (30) days after the end of the initial quarter subject to the Certificate of Participation, the manufacturer will provide the Missouri Senior Rx Program with the information for all covered outpatient drugs for the initial quarter containing the data shown in Appendix A of the Certificate of Participation. This list shall be updated quarterly, within thirty (30) days of the end of each quarter. The manufacturer's quarterly report will include all new drug NDC numbers and continue to list those NDC numbers for drugs no longer marketed. If no sales are reported by the manufacturer during a quarter, the AMP last reported shall be used in calculating rebates.

A. Manufacturers submitting data for six (6) or more drug products agree to submit the data via diskette or electronic data interchange (EDI) in a format acceptable to the Missouri Senior Rx Program. Manufacturers submitting data for five (5) or fewer drug products may report the data via diskette, EDI or paper.

B. Manufacturers failing to submit required data in the agreed upon format within the specified time period shall be liable

for a civil penalty in the amount of one thousand dollars (\$1,000) for each day that the data in the agreed upon format is late;

2. Calculate and, except as provided under section 208.556.3, RSMo to make a timely rebate payment to the Missouri Senior Rx Program for the manufacturer's covered outpatient drugs dispensed during a quarter under the program;

3. Within thirty (30) days of the manufacturer's receipt of the utilization data from the Missouri Senior Rx Program, the manufacturer must submit the rebate payment accompanied by a detailed invoice showing the calculated rebate amount per unit, and total rebate amount paid for each NDC using the federal rebate reporting format of Reconciliation of State Invoice (ROSI) and Prior Quarter Adjustment (PQAS) shown in Appendix B of the Certificate of Participation. Items in dispute must be identified on the ROSI and PQAS using federal coding shown in Appendix C of the Certificate of Participation.

A. Rebate payments not made within the specified time frames will be subject to an interest charge of one percent (1%) per month. This includes payments due on disputed units;

4. Continue to make a rebate payment on all of its covered outpatient drugs for as long as the Certification of Participation is in force and as long as such covered outpatient drugs are dispensed under the manufacturer's NDC number;

5. The manufacturer will be responsible for rebates on claims for products that were dispensed within one (1) year of the date that the claim was paid by the DHSS for the Missouri Senior Rx Program;

6. The manufacturer shall maintain records that will permit the Missouri Senior Rx Program to verify the rebate calculation and payment. The Missouri Senior Rx Program may conduct audits to verify the rebate calculation and payment;

7. Comply with the dispute resolution process as specified in section (4) of this regulation; and

8. Comply with the conditions in section 208.556, RSMo including any amendments or implementing regulations the Missouri Senior Rx Program deems necessary.

(3) Missouri Senior Rx Program Responsibilities.

(A) The Missouri Senior Rx Program, each quarter, must promptly notify pharmacies of those manufacturers that have entered into a rebate agreement. The Missouri Senior Rx Program must also promptly notify pharmacies regarding any changes to the list of covered outpatient drugs.

(B) The Missouri Senior Rx Program will report utilization information to the manufacturer, within sixty (60) days of the last day of each quarter subsequent to the effective date of the Certificate of Participation and in a manner prescribed by the Missouri Senior Rx Program. If the Missouri Senior Rx Program does not submit a rebate invoice to the manufacturer within one (1) year after the rebate period ends, the manufacturer is not required to pay a rebate on drugs approved and processed during that rebate period.

(C) The Missouri Senior Rx Program shall maintain electronic claim records for the most recent four (4) quarters that will assist manufacturers in verifying the utilization information provided. The Missouri Senior Rx Program will also make available claims detail data supporting the invoice utilization and/or remaining balances in a mutually agreeable format upon request of the manufacturer.

(D) The Missouri Senior Rx Program will cooperate with manufacturers by performing pharmacy audits should such audits be required to resolve disputes.

(E) The Missouri Senior Rx Program may audit manufacturer calculations to verify the AMPs and URAs reported.

(4) Dispute Resolution.

(A) In the event that for any quarter a discrepancy is noted by the manufacturer in the Missouri Senior Rx Program's utilization

data, the manufacturer must provide written notice of the discrepancy, by NDC number, to the Missouri Senior Rx Program. Discrepancies in utilization data must be reported to Missouri Senior Rx Program prior to the due date for payment of rebate for that quarter.

(B) If the manufacturer in good faith disputes the Missouri Senior Rx Program utilization information, the manufacturer shall pay that portion of the rebate amount claimed which is not disputed no later than the date of payment of the rebate for the quarter as prescribed in Section II (c) of the Certificate of Participation. If the dispute is resolved after negotiation, the balance due, if any, will be paid or credited by the manufacturer or the Missouri Senior Rx Program by the due date of the next quarterly payment.

(C) The Missouri Senior Rx Program and the manufacturer will use their best efforts to resolve the discrepancy within sixty (60) days of receipt of written notification. Should an audit of pharmacy records be required, the Missouri Senior Rx Program will provide data to the manufacturer to identify pharmacy providers to be audited by the Missouri Senior Rx Program.

(D) In the event that the Missouri Senior Rx Program and the manufacturer are not able to resolve a discrepancy within one hundred eighty (180) days, the manufacturer may appeal to the commission by presenting its position to the commission. This appeal shall be in writing with all supporting documentation to support the manufacturer's position. A hearing before the commission will be scheduled within ninety (90) days of receipt of the appeal from the manufacturer with a decision rendered within fourteen (14) days of the hearing before the commission. The commission's decision is considered final.

(5) Confidentiality Provisions.

(A) Information disclosed by the manufacturer in connection with the Certification of Participation is confidential and will not be disclosed, except as required by state and federal law.

(B) The manufacturer will maintain the confidentiality of the Missouri Senior Rx Program utilization information and use such information only for purposes approved by the commission. If the manufacturer audits this information or receives additional information on such data, the information shall also be held confidential. The manufacturer agrees to abide by applicable state confidentiality statutes, regulations and other properly promulgated policy.

(C) Notwithstanding the nonrenewal or termination of the Certificate of Participation for any reason, these confidentiality provisions will remain in full force and effect.

(D) The manufacturer and Missouri Senior Rx Program shall inform and train, if necessary, its respective employees, agents, advisors, consultants and officials regarding the confidential nature of such data and shall cause such persons (including any board or committee) to keep such data and information confidential.

(6) Nonrenewal and Termination.

(A) The Certificate of Participation shall be effective for an initial period of one (1) year from the date noted in Section IX of the Certificate of Participation and shall automatically be renewed for additional terms of one (1) year, unless the manufacturer or the Missouri Senior Rx Program gives sixty (60) days written notice of intent not to renew.

(B) The manufacturer may terminate its Certificate of Participation in the Missouri Senior Rx Program for any reason, and such termination shall become effective the first day of the first quarter beginning sixty (60) days after the manufacturer gives written notice requesting termination.

(C) The Missouri Senior Rx Program may terminate the Certificate of Participation for violations of the provisions within the Certificate of Participation or other good cause upon sixty (60) days prior written notice.

(7) General Provisions.

(A) Notice and reports required to be given pursuant to the terms and provisions of this certification will be sent in writing unless mutually agreed otherwise.

1. Notice and Reports to the Missouri Senior Rx Program will be sent to:

Department of Health and Senior Services
Executive Director
Missouri Senior Rx Program
205 Jefferson Street, 13th Floor
P O Box 570
Jefferson City, MO 65102-0570

2. Notice and data concerning data transfer and rebate payments will be sent to:

Division of Medical Services
PO Box 6500
Jefferson City, MO 65102-6500

3. Notice to manufacturer will be sent to the address provided to the Missouri Senior Rx Program by the manufacturer.

(B) In the event of a transfer in ownership of the manufacturer, the certification is automatically assigned to the new owner subject to the conditions specified in the Certificate of Participation.

(C) Nothing in this application for a Certificate of Participation or the Certificate of Participation shall be construed to require or authorize the Missouri Senior Rx Commission, DHSS, DMS or the application for or recipient of a Certificate of Participation to commit any act contrary to law. If any provision of this application for the Certificate or the Certificate of Participation is found to be invalid by a court of law, the application for the Certificate of Participation or the Certificate of Participation shall be construed in all respects as if the invalid or unenforceable provision were eliminated without any effect on any provision.

(D) Nothing in this application for a Certificate of Participation or the Certificate of Participation shall be construed as a waiver or relinquishment of any legal rights of the manufacturer or the Missouri Senior Rx Commission, the Social Security Act, other federal laws or state laws.

(E) The terms DHSS and DMS and manufacturer incorporate any contractors or agents thereof which fulfill responsibilities pursuant to the Certificate of Participation unless otherwise specifically provided for in the Certificate of Participation.

(F) In the event that a due date falls on a weekend, or a federal or state holiday, the report or other item will be due on the first business day following that weekend or holiday.

*AUTHORITY: section 208.553.3(5), RSMo Supp. 2001. Emergency rule filed Feb. 15, 2002, effective March 1, 2002 and expires Aug. 27, 2002. A proposed rule covering this same material is published in this issue of the **Missouri Register**.*