

**OFFICIAL TEXT FOR REVISION**

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USE THIS ELECTRONIC VERSION FOR THIS RULE PROJECT. DO NOT USE TEXT FROM THE SECRETARY OF STATE'S WEB SITE

**'STRIKETHROUGH' TEXT YOU ARE REMOVING**  
**USE 'UNDERLINE' FOR NEW TEXT YOU ARE ADDING**

Example: ~~Strikethrough-first~~, underline second.

All rulemaking materials **MUST** be sent to the OLA as soon as possible upon completion or **4 weeks** prior to the SOS filing date.

Rulemaking materials include: official text changes, statement of reasonable necessity, fiscal impact statement, small business impact, and Medicaid performance-based rulemaking information (if applicable)

All Rule Forms are on the OURS web site under the Director's Office page at:  
<http://ours.hhs.mt.gov/director/index.shtml>

PLEASE CONTACT GWEN KNIGHT WITH ANY QUESTIONS, EXT 444-4094  
OR TODD OLSON, EXT 444-9503.

THIS TEXT IS BEING PROVIDED AT THE REQUEST OF: Dani Feist  
DATE TEXT PROVIDED: 7/30/18

37.86.1102 OUTPATIENT DRUGS, REQUIREMENTS (1) These requirements are in addition to those contained in ARM 37.85.401 through 37.85.415.

(2) For purposes of Medicaid reimbursement, outpatient drugs may not be filled or refilled without the authorization of the physician or other licensed practitioner who is authorized by law to prescribe drugs and is recognized by the Medicaid program.

(3) The department will only participate in the payment of legend and over-the-counter drugs listed on the department drug formulary, as determined by the Medicaid Drug Formulary Committee established by the department. The formulary committee is the Drug Use Review Board, established and operating in accordance with 42 USC 1396r-8 (2016), which governs Medicaid drug programs. The drug formulary includes a preferred drug list. Prescribers must prescribe from the preferred drug list if medically appropriate.

(a) The PDL includes drugs subject to a Centers for Medicare and Medicaid Services (CMS) approved supplemental rebate agreement between the manufacturer and the department. Drugs in the same therapeutic class as those identified on the preferred drug list but not identified as a preferred drug are subject to prior authorization as outlined in (6)(c).

(4) The inappropriate use of drugs, as determined by professional review, may result in the imposition of a limitation upon the quantities of medications which are payable by the medical assistance program. Retroactive limitation is not

applied, unless the involved pharmacy has knowledge or can reasonably be expected to have had knowledge of the inappropriate use of drugs by the member.

(5) Each prescription must be dispensed in the quantity ordered except that:

(a) Prescriptions for which a specific quantity has not been ordered must be dispensed in sufficient quantities to cover the period of time for which the condition is being treated except for:

(i) injectable antibiotics, which may be dispensed in sufficient quantities to cover a three-day period.

(ii) opioids, for opioid naïve members in accordance with ARM 37.86.1103.

(b) Notwithstanding the above, maintenance medications may be dispensed in quantities sufficient for a 90-day supply or 100 units, whichever is greater. Other medications may not be dispensed in quantities greater than a 34-day supply. The department maintains a list of current drug classes which are considered maintenance medications and are posted on the department's web site at <http://medicaidprovider.mt.gov>.

(6) The department does not participate in the payment of a prescription drug:

(a) which the Secretary of Health and Human Services (HHS) has determined is less than effective for all conditions of use prescribed, recommended or suggested in the drug's labeling;

(b) that is not subject to a rebate agreement between the manufacturer and the secretary of HHS as required by 42 USC 1396r-8 (2016); and

(c) that does not meet prior authorization criteria as determined by the Medicaid Drug Formulary Committee, established and operating in accordance with 42 USC 1396r-8 (2016), without the existence of a prior authorization request approved by the department or its designated representative. A list of drugs subject to prior authorization, known as the prior authorization drug list, will be provided to interested Medicaid providers.

(7) The department may pay for nonrebutable API bulk powders and excipients compounded in accordance with ARM 37.86.1105(5).

(8) The drug formulary, PDL, and the prior authorization drug list is updated by the department on a monthly basis, on the last day of each month. A copy of the most current listings may be obtained from the department web site at [www.dphhs.mt.gov](http://www.dphhs.mt.gov), or by writing to the Department of Public Health and Human Services, Health Resources Division, Allied Health Services Bureau, 1400 Broadway, P.O. Box 202951, Helena, MT 59620-2951.

(9) The department has a drug rebate program administered in accordance with 42 USC 1396r-8 (2016) and CMS drug program state releases, CMS drug manufacturer releases, and the National Drug Rebate Agreement in effect in 2008. The department adopts and incorporates by reference the National Drug Rebate Agreement (2008). A copy of all documents incorporated by reference in this rule may be obtained from the department web site at [www.dphhs.mt.gov](http://www.dphhs.mt.gov), or by writing to the Department of Public Health and Human Services, Health Resources Division, Allied Health Services Bureau, 1400 Broadway, P.O. Box 202951, Helena, MT 59620-2951.

(a) Pharmaceutical manufacturers, hereafter referred to as the manufacturer, must make rebate payments to the department for each calendar quarter within 30 days after receiving from the department the Medicaid utilization information defined in their federal rebate agreement. The manufacturer is responsible for timely payment of the rebate within 30 days of receiving, at a minimum, information on the number of units paid, by NDC number.

(b) 42 USC 1396r-8 (2016) establishes the requirements that must be met by the department, drug manufacturers, and providers in order for providers to receive reimbursement for outpatient drugs that have been dispensed. This statute describes rebate agreements, covered drugs, prior authorization, reimbursement limits, and drug use review programs.

(10) A provider must maintain a signature log to act as proof that the dispensed medication has been received by the member or an individual acting on behalf of the member. The member, or an individual acting on behalf of the member, must sign the log each time that they receive a prescription drug from a pharmacy provider. For prescription drugs delivered to a nursing facility, the individual charged with ensuring the security of pharmaceutical supplies may sign the log after verifying delivery of all prescription drugs.

(11) The department uses the following procedures to develop the preferred drug list (PDL):

(a) The department performs a pharmacoeconomic analysis of the Medicaid Pharmacy Program and identifies therapeutic classes of drugs for possible PDL inclusion.

(b) The department and the Drug Use Review (DUR) Board/Formulary Committee members consider recommendations and determine which therapeutic drug classes will be reviewed at a meeting of the committee. Notice of the meeting and the therapeutic drug class to be considered is posted on the department's web site in advance of the meeting date.

(c) The department performs drug class reviews using peer-reviewed literature, established evidence-based practice methods, and local clinicians to interpret and apply practical experience to the structured evidence reviews. The department also conducts supplemental rebate negotiations.

(d) The committee combines its members' evaluations and the evaluations from the department to consider equivalent products within the drug class. Information used by the department and its contractors is available to the public prior to the meeting. During the meeting, the committee also hears comments from interested parties.

(e) The committee recommends to the department which preferred agents should be selected for the specific therapeutic class.

(f) The department makes a final decision and posts its decision on the department's web site. (History: 53-2-201, 53-6-113, MCA; IMP, 53-2-201, 53-6-101, 53-6-113, 53-6-141, MCA; NEW, 1980 MAR p. 2978, Eff. 11/29/80; AMD, 1982 MAR p. 105, Eff. 1/29/82; AMD, 1987 MAR p. 895, Eff. 7/1/87; AMD, 1988 MAR p. 753, Eff. 5/1/88; AMD, 1991 MAR p. 1039, Eff. 6/28/91; AMD, 1994 MAR p. 2443, Eff. 8/26/94; AMD, 1998 MAR p. 495, Eff. 2/13/98; TRANS, from SRS, 2000 MAR p. 481; EMERG, AMD, 2003 MAR p. 999, Eff. 5/9/03; AMD, 2004 MAR p. 1489, Eff.

7/2/04; AMD, 2008 MAR p. 1157, Eff. 7/1/08; AMD, 2008 MAR p. 2669, Eff. 1/1/09;  
AMD, 2011 MAR p. 2416, Eff. 11/11/11; AMD, 2016 MAR p. 1065, Eff. 7/1/16.)