

Emergency Rule

Title 13—DEPARTMENT OF SOCIAL SERVICES Division 70—MO HealthNet Division Chapter 20—Pharmacy Program

EMERGENCY AMENDMENT

13 CSR 70-20.070 Drug Reimbursement Methodology. The Department of Social Services is removing current sections (3), (5), and (6), amending the new section (3), adding a new section (4), and renumbering as necessary.

PURPOSE: The purpose of this emergency amendment is to remove the outdated reimbursement information for covered drugs and completely remove the reimbursement information for 340B providers. The 340B reimbursement information is being moved concurrently with this amendment to proposed rule 13 CSR 70-20.075.

EMERGENCY STATEMENT: This emergency amendment informs the public that the methodology for reimbursement of drugs purchased through the 340B program will be placed in a new regulation, 13 CSR 70-20.075 340B DRUG PRICING PROGRAM, on July 1, 2021. The MO HealthNet program is of critical importance to the health, safety, and welfare of its participants, and it is imperative to the department's mission that it continue to provide MO HealthNet services while not jeopardizing the federal and state funding available to all MO HealthNet participants. This emergency amendment is the result of negotiations between the department and the Center for Medicare and Medicaid Services (CMS) regarding the department's compliance with the CMS Covered Outpatient Drug Rule (42 CFR Part 447 Subpart I). As a component of this rule, the 340B program allows 340B-covered entities to purchase drugs at significantly reduced prices. The methodology for reimbursement of drugs purchased through the 340B program must now be based on actual acquisition cost and approved by CMS. The prior reimbursement methodology must be revised to reflect this actual acquisition cost methodology. The department's negotiations with CMS concluded on this issue in March 2021, and this emergency amendment must be implemented urgently so that the MO HealthNet Division is in compliance with federal Medicaid legal requirements implemented by CMS. The negotiations allow MO HealthNet to reimburse Physician Administered Drugs purchased through the 340B program at a higher rate than non-Physician Administered Drugs purchased through the 340B Program. The higher rate is designed to offset a portion of the loss in revenue to Covered Entities. The MO HealthNet Division has a compelling government interest in paying for drugs purchased through the 340B program in accordance with the CMS Covered Outpatient Drug Rule (42 CFR Part 447) in order to meet federal funding participation requirements. In State Fiscal Year 2020 MO HealthNet reimbursed \$115,516,774 in 340B purchased drugs, the federal share was approximately \$75,765,141.73. Failure to promulgate the emergency rule could result in a disallowance of the federal share, shifting significant costs to the State of Missouri General Revenue Fund. The shift of these costs will result in funds being pulled from other portions of the budget for the State of Missouri, impacting public health, safety and welfare of Missouri residents. The scope of this emergency amendment is limited to the circumstances creating the emergency and complies with the protections extended by the Missouri and United States Constitutions. The MO HealthNet Division believes that this emergency rule is fair to all interested persons and parties under the circumstances. This emergency amendment was filed April 26, 2021, becomes effective July 1, 2021, and expires February 24, 2022.

[(3) Reimbursement for covered drugs dispensed between April 1, 2017, and December 15, 2018, will be determined by applying the following hierarchy method:

- (A) Federal Upper Limit (FUL) price; if there is no FUL;*
- (B) Missouri Maximum Allowed Cost (MAC); if no FUL or*

MAC;

(C) Wholesale Acquisition Cost (WAC) minus three and one-tenth percent (3.1%); or

(D) The usual and customary (U&C) charge submitted by the provider if it is lower than the chosen price (FUL, MAC, or WAC).]

[(4)](3) Effective December 16, 2018, reimbursement for covered drugs will be determined by applying the following hierarchy method:

(A) National Average Drug Acquisition Cost (NADAC); if there is no NADAC;

(B) Missouri Maximum Allowed Cost (MAC); if no NADAC or MAC;

(C) Wholesale Acquisition Cost (WAC); or

(D) The usual and customary (U&C) charge submitted by the provider if it is lower than the chosen price (NADAC, MAC, or WAC). U&C is defined as the provider's charge to the general public that reflects all advertised savings, discounts, special promotions, or other programs including membership based discounts initiated to reduce prices for product costs available to the general public, a special population, or an inclusive category of customers.

(4) Reimbursement for covered drugs for 340B providers as defined in 42 USC 256b(a)(4) and 42 USC 1396r-8(a)(5)(B) who carve-in for Medicaid will be calculated according to 13 CSR 70-20.075.

[(5) Between April 1, 2017, and December 15, 2018, reimbursement for covered drugs for 340B providers as defined by the Public Health Service Veterans Health Care Act of 1992 who carve-in for Medicaid will be determined by applying the following method:

(A) Wholesale Acquisition Cost (WAC) minus forty-nine percent (49%); or

(B) The usual and customary (U&C) charge submitted by the provider if it is lower.

(6) Effective December 16, 2018, reimbursement for covered drugs for 340B providers as defined by the Public Health Service Veterans Health Care Act of 1992 who carve-in for Medicaid will be determined by applying the following method:

(A) Wholesale Acquisition Cost (WAC) minus twenty-five percent (25%); or

(B) The usual and customary (U&C) charge submitted by the provider if it is lower.]

[(7)](5) The professional dispensing fee will be calculated according to 13 CSR 70-20.060.

AUTHORITY: sections 208.153, 208.201, and 660.017, RSMo 2016, and section 208.152, RSMo Supp. [2018]2020. This rule was previously filed as 13 CSR 40-81.150. Original rule filed April 23, 1979, effective Aug. 11, 1979. For intervening history, please consult the Code of State Regulations. Emergency amendment filed April 26, 2021, effective July 1, 2021, expires Feb. 24, 2022. An emergency amendment and a proposed amendment covering this same material will be published in the June 1, 2021, issue of the Missouri Register.

PUBLIC COST: This emergency amendment will not cost state agencies or political subdivisions more than five hundred dollars (\$500) in the time the emergency is effective.

PRIVATE COST: This emergency amendment will not cost private entities more than five hundred dollars (\$500) in the time the

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emergency is effective.