

Emergency Rule

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

EMERGENCY RULE

13 CSR 70-20.075 340B Drug Pricing Program

PURPOSE: This rule establishes the payment methodology for 340B-covered entities as defined in section 1927(a)(5)(B) of the Social Security Act that choose to carve-in Medicaid.

EMERGENCY STATEMENT: This emergency rule informs the public that the reimbursement methodology for drugs purchased through the 340B program will change on July 1, 2021. The 340B program allows Covered Entities to purchase drugs at significantly reduced prices. The methodology for reimbursement of drugs purchased through the 340B program must be based on actual acquisition cost and approved by the Center for Medicare and Medicaid Services (CMS). The prior reimbursement methodology must be revised to reflect actual acquisition cost. This emergency rule must be implemented urgently so that the MO HealthNet Division is in compliance with federal Medicaid legal requirements implemented through CMS. 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. 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 Subpart I) 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. This 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. The department's negotiations with CMS concluded on this issue in March 2021, and this emergency rule 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 scope of this emergency rule 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 rule was filed April 26, 2021, becomes effective July 1, 2021, and expires February 24, 2022.

(1) 340B covered entities that choose to carve-in Medicaid must provide the Health Resources and Services Administration (HRSA) with their National Provider Identification (NPI) and their MO HealthNet Division (MHD) provider number for each site that carves in for inclusion in the HRSA Medicaid Exclusion File.

(2) 340B covered entities are required to identify 340B purchased drugs at the claims level using the following codes:

(A) Point-of-sale pharmacy claims: Submission Clarification Code

(SCC) 20; and

(B) Medical and outpatient claims: Modifier JG or TB.

(3) Failure to include the appropriate submission clarification code or modifier on a 340B purchased drug will result in the MHD collecting rebate on the claim and may subject the covered entity to audit penalties. The MHD will deny claims from providers who submit an SCC of 20 or 340B modifier but have not notified HRSA of carve-in status.

(4) Effective July 1, 2021, reimbursement for 340B identified covered drugs for 340B providers as defined by 42 USC 256b(a)(4) and 42 USC 1396r-8(a)(5)(B) who carve-in for Medicaid will be determined by applying the following method:

(A) 340B purchased drugs dispensed by pharmacy providers will be reimbursed at their actual acquisition cost, up to the 340B Maximum Allowable Cost (MAC) (calculated ceiling price) plus a professional dispensing fee. Covered entities are required to bill no more than their actual acquisition cost plus the professional dispensing fee.

1. The 340B MAC (calculated ceiling price) is defined as the Average Manufacturer Price (AMP) minus Unit Rebate Agreement (URA).

(B) Physician-administered drugs purchased through the 340B program will be reimbursed the lesser of the Physician-Administered 340B MAC or the actual acquisition cost submitted by the provider. A professional dispensing fee is not applied to physician-administered drugs.

1. The Physician-Administered 340B MAC is calculated by adding six percent (6%), up to six hundred dollars (\$600), to the calculated ceiling price.

(5) 340B contract pharmacies are not covered under this policy and must carve-out Medicaid from their 340B operation unless MHD approves an exception.

AUTHORITY: sections 208.153, 208.201, and 660.017, RSMo 2016. Emergency rule was filed April 26, 2021, becomes effective July 1, 2021, and expires February 24, 2022. An emergency rule and a proposed rule covering this same material will be published in the June 1, 2021, issue of the Missouri Register.

PUBLIC COST: This emergency rule will cost state agencies or political subdivisions an estimated one-time implementation cost of twenty-five thousand dollars (\$25,000) and a cost of forty-five thousand dollars (\$45,000) in the time the emergency is effective.

PRIVATE COST: This emergency rule will cost private entities an estimated eighteen million, three hundred forty-six thousand and five hundred eighty-four dollars (\$18,346,584) in the time the emergency is effective.

Emergency Rule

FISCAL NOTE PUBLIC COST

- I. Department Title:** Title 13–Department of Social Services
Division Title: Division 70–MO HealthNet Division
Chapter Title: Chapter 20–Pharmacy Programs

Rule Number and Name:	13 CSR 70-20.075 340B Drug Pricing Program
Type of Rulemaking:	Emergency Rule

II. SUMMARY OF FISCAL IMPACT

Affected Agency or Political Subdivision	Estimated Cost of Compliance in the Aggregate
Missouri Department of Social Services- MO HealthNet	One-time implementation cost of \$25,000 Ongoing cost for July 1-December 31, 2021 of \$45,000

III. WORKSHEET

MO HealthNet will utilize a contractor to establish the 340B MAC Rates. This contract will have a one-time implementation cost of approximately \$25,000 in addition to the ongoing quarterly file delivery cost of approximately \$45,000 for July 1-December 31, 2021.

IV. ASSUMPTIONS

The state assumes an estimated savings of \$18,346,584 for July 1-December 31, 2021.

Emergency Rule

FISCAL NOTE PRIVATE COST

- I. Department Title:** Title 13–Department of Social Services
Division Title: Division 70–MO HealthNet Division
Chapter Title: Chapter 20–Pharmacy Programs

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II. SUMMARY OF FISCAL IMPACT

Estimate of the number of entities by class which would likely be affected by the adoption of the rule:	Classification by types of the business entities which would likely be affected:	Estimate in the aggregate as to the cost of compliance with the rule by the affected entities:
180	Enrolled MO HealthNet Providers enrolled in the 340B program	Estimated costs for July 1, 2021-December 31, 2021: \$18,346,584

III. WORKSHEET

Beginning 7/1/2021, the new reimbursement methodology for 340B purchased medications will be the lesser of the 340B Maximum Allowed Cost (MAC) based on the calculated ceiling price for medications or the providers usual and customary charge. Pharmacy providers will also receive the standard dispensing fee. All other providers will receive the Physician-Administered 340B MAC which is calculated by adding 6%, up to \$600, to the calculated ceiling price. The current payment to 340B providers is Wholesale Acquisition Cost (WAC) minus 25%. For the timeframe of 10/1/19 – 9/30/2020, 340B providers were reimbursed a total of \$114,365,477. It is anticipated under the new methodology the estimated total reimbursement would be \$78,479,826 resulting in an annual public savings. These figures do not include the dispensing fee, which is covered under 13 CSR 70-20.060.

IV. ASSUMPTIONS

New reimbursement amounts were applied to claims processed from 10/1/2019 – 9/30/2020.