

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

PROPOSED AMENDMENT

13 CSR 70-20.075 340B Drug Pricing Program. The Department of Social Services – MO HealthNet Division is amending sections (1), (2), (3), (4), (5), and adding section (6).

PURPOSE: This amendment simplifies and clarifies the language of the current rule and establishes a carve-out list of medications that are not reimbursable if purchased through the 340B program.

(1) *[340B-c]* 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. *[The]* MHD requires the *[MO HealthNet]* MHD provider number to be included on the Medicaid Exclusion File to identify providers that carve-in Medicaid and to prevent duplicate discounts. **A duplicate discount is defined as a covered entity receiving a discounted drug through the 340B program from the manufacturer, and MHD receives a rebate through the Medicaid Drug Rebate Program from the manufacturer for the same claim. Covered entity is defined in Section 376.414.1(2), RSMo.**

(2) *[340B-c]* Covered entities *[are required to]* **must** identify 340B-purchased drugs *[at the claims level]* **using the Submission Clarification Code or modifier code on each claim that was 340B purchased.** *[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]* **identifier** on a 340B-purchased drug will result in the MHD collecting a rebate on the claim, **resulting in a potential duplicate discount.** *[and]* **A duplicate discount** may subject the covered entity to audit penalties. *[The]* MHD will deny claims **identified as 340B-purchased drugs at the claim level** from providers who *[submit an SCC of 20 or 340B modifier but have not notified]* **have yet to notify** HRSA of carve-in status.

(4) *[Effective July 1, 2021, r]* **Reimbursement** for 340B-identified covered drugs for 340B providers as defined *[by 42 U.S.C. 256b(a) (4) and 42 U.S.C. 1396r-8(a)(5)(B)]* **in Section 376.414.1(2), RSMo**, who carve-in for Medicaid will be determined by applying the following method:

(A) **MHD will reimburse** 340B-purchased drugs dispensed by pharmacy providers *[will be reimbursed]* at their actual acquisition cost, up to the 340B Maximum Allowable Cost (**340B MAC**) (calculated ceiling price) plus a professional dispensing fee. Covered entities *[are*

required to **must** bill no more than their actual acquisition cost plus the professional dispensing fee.

1. **MHD defines [T]the 340B MAC (calculated ceiling price) [is defined]as the Average Manufacturer Price (AMP) minus Unit Rebate Agreement (URA) as reported by the Centers for Medicare & Medicaid (CMS) quarterly;**

2. **MHD defines [A]actual acquisition cost [is defined]as the invoice cost for the [NDC]National Drug Code (NDC) per billing unit. This does not include timely pay discounts or discounts paid as a rebate on a separate invoice for volume-based purchases; and**

3. MHD calculates the professional dispensing fee according to 13 CSR 70-20.060.

(B) **MHD will reimburse [P]physician-administered drugs purchased through the 340B program [will be reimbursed]at the lesser of the physician-administered 340B MAC or the actual acquisition cost submitted by the provider. MHD does not apply [A]a professional dispensing fee [is not applied]to physician-administered drugs.**

1. *[The]MHD adds six percent (6%), up to six hundred dollars (\$600), to the 340B MAC to calculate the [P]physician-administered 340B MAC. [is calculated by adding six percent (6%), up to six hundred dollars (\$600), to the calculated ceiling price.]*

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

(6) **MHD may carve-out certain medications and categories of medications from 340B participation for MHD reimbursement. Medications subject to the carve-out will be reimbursed according to 13 CSR 70-20.070. The following medications and categories of medications are carved-out of reimbursement through the 340B program:**

- (A) **Drugs approved by the FDA for the treatment of obesity; and**
- (B) **Cell and Gene Therapies.**

AUTHORITY: sections 208.153, 208.201, and 660.017, RSMo 2016. Emergency rule filed April 26, 2021, effective July 1, 2021, expired Feb. 24, 2022. Original rule filed April 26, 2021, effective Nov. 30, 2021. Emergency amendment filed November 21, 2024, effective December 9, 2024, expires June 6, 2025. Amended: Filed November 21, 2024.*

**Original authority: 208.153, RSMo 1967, amended 1973, 1989, 1990, 1991, 2007, 2012; 208.201, RSMo 1987, amended 2007; and 660.017, RSMo 1993, amended 1995.*

PUBLIC COST: This proposed amendment will cost state agencies or political subdivisions two million, ninety-six thousand, one hundred fifty-nine dollars (\$2,096,159) in the aggregate.

PRIVATE COST: This proposed amendment will cost private entities nine million, five hundred forty-nine thousand, one hundred sixty-nine dollars (\$9,549,169) in the aggregate.

*NOTICE TO SUBMIT COMMENTS: Anyone may file a statement in support of or in opposition to this proposed amendment with the Department of Social Services, Legal Services Division-Rulemaking, PO Box 1527, Jefferson City, MO 65102-1527, or by email to Rules.Comment@dss.mo.gov. To be considered, comments must be received within thirty (30) days after publication of this notice in the **Missouri Register**. No public hearing is scheduled.*