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

EMERGENCY AMENDMENT

13 CSR 70-20.075 340B Drug Pricing Program. The division is amending sections (1)–(5), and adding new 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.

*EMERGENCY STATEMENT: The emergency amendment informs the public that MO HealthNet Division (MHD) is excluding certain outpatient drugs from reimbursement through the 340B Program. This emergency amendment is necessary to protect governmental interest to MHD as it will realize a three-million-dollar savings during the time this emergency is effective, which will contribute to a financially sustainable Medicaid program in Missouri. MHD will begin to cover drugs approved by the FDA for the treatment of obesity in January 2025 and will start entering into supplemental rebate contracts for those drugs and value-based contracts for cell and gene therapies. When providers purchase these medications through the 340B program, federal law prohibits MHD from collecting supplemental rebates, causing MHD to pay a higher net cost. MHD will not be able to collect supplemental rebates for these outpatient drugs without this emergency amendment. As a result, MHD finds a compelling governmental interest, which requires this emergency action. 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**. MHD believes that this emergency amendment is fair to all interested persons and parties under the circumstances. Emergency amendment filed November 21, 2024, becomes effective December 9, 2024, and expires June 6, 2025.*

(1) *[340B-c]***C**overed 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]***C**overed entities *[are required to]* **must** identify 340B-purchased drugs *[at the claims level the following codes:]* **using the Submission Clarification Code or modifier code on each claim that was 340B-purchased.**

[(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 *[and]***, resulting in a potential duplicate discount. 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]***R**eimbursement 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. *[The]* **MHD defines 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. *[Actual]* **MHD defines 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; and

(B) **MHD will reimburse** *[P]***p**hysician-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. *[A]* **MHD does not apply 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]* **MHD adds six percent (6%), up to six hundred dollars ($600), to the 340B MAC to calculate the physician-administered 340B MAC**.

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

(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***, and section 208.153, RSMo Supp. 2024**. 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 Nov. 21, 2024, effective Dec. 9, 2024, expires June 6, 2025. An emergency amendment and a proposed amendment covering the same material will be published in the Jan. 2, 2025, issue of the **Missouri Register**.*

PUBLIC COST: This emergency amendment will cost public entities $1,048,079.50 in the time the emergency amendment is effective.

PRIVATE COST: This emergency amendment will cost private entities $4,774,584.50 in the time the emergency amendment is effective.

FISCAL NOTE
PUBLIC COST

I. Please include clear instructions regarding what information to include in this field:
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 Amendment

II. SUMMARY OF FISCAL IMPACT

Affected Agency or Political Subdivision	Estimated Cost of Compliance in the Aggregate
Department of Social Services MO HealthNet Division	• Estimated Cost for Public Covered Entities January 1, 2025 – June 30, 2025 = $1,048,079.50 • Estimated Ongoing Cost for Public Covered Entities = $2,096,159 • Estimated Savings for MHD from January 1, 2025 – June 30, 2025 = $4,252,743 • Estimated Ongoing Annual Savings to MHD = $8,505,486 in savings

III. WORKSHEET

Cell and Gene Therapy Worksheet MHD Costs/Savings:

Number of cell and gene therapy claims billed to the MO HealthNet Division (MHD) during SFY24	101
Number of 340B purchased cell and gene therapy claims billed to MHD by Covered Entities during SFY24	3
The amount reimbursed for 340B purchased cell and gene therapy claims billed to MHD by Covered Entities during SFY24 (proxy for CE's actual acquisition cost)	$5,985,015
The amount that MHD would reimburse for the same claims had they not been purchased through the 340B program (proxy for CE's actual acquisition cost if not purchased through 340B program):	$7,708,824
The difference in actual acquisition cost for cell and gene therapy when utilizing non-340B stock compared to 340B stock	$1,723,809
The increased rebate revenue based on a weighted average of supplemental rebates (32.2% of ingredient cost):	$2,482,241

Updated 01/31/2021

The increased rebate revenue based on the average of federal rebates (based on the difference between 340B and non-340B reimbursement for the 3 claims):	$1,723,809

Anti-Obesity Worksheet MHD Costs/Savings:

Anticipated Prescriptions for an Anti-obesity Agent for 1 year	170,000
Average cost of claim for Anti-Obesity Agent	$1,041.00
Average Supplemental Rebate Percentage (Based on weighted average of current supplemental rebate contracts for all drugs)	32.20%
Anticipated Percentage of Anti-Obesity Agents filled at 340B Covered Entities using 340B stock	10.57%
Additional Supplemental Rebate Captured by not allowing 340B Covered Entities to use 340B stock for MHD Participants	$6,023,245
Additional Federal Rebate Captured by not allowing 340B Covered Entities to use 340B stock for MHD Participants (53.04%)	$9,921,519

Cell and Gene Therapy Worksheet Public and State-Owned Covered Entities:

Number of cell and gene therapy claims billed to the MO HealthNet Division (MHD) during SFY24	101
Number of 340B purchased cell and gene therapy claims billed to MHD by Covered Entities during SFY24	3
The amount reimbursed for 340B purchased cell and gene therapy claims billed to MHD by Covered Entities during SFY24 (proxy for CE's actual acquisition cost)	$5,985,015
The amount that would have been reimbursed for the same claims had they not been purchased through the 340B program (proxy for CE's actual acquisition cost if not purchased through 340B program)	$7,708,824
The difference in actual acquisition cost for cell and gene therapy when utilizing non-340B stock compared to 340B stock	$1,723,809

Anti-Obesity Worksheet Public and State-Owned Covered Entities:

Anticipated Prescriptions for an Anti-obesity Agent for 1 year	170,000

Average cost of claim for Anti-Obesity Agent	$1,041
Average Federal Rebate Percentage for all MHD Drug Claims	53.04%
Anticipated Percentage of Anti-Obesity Agents filled at 340B Covered Entities using 340B stock	10.57%

Updated 01/31/2021

Increased purchase price of anti-obesity agents when utilizing non-340B compared to 340B (amount to be offset by increased MO HealthNet reimbursement)	$9,921,519

MHD Costs/Savings

Change	Estimated Cost
Cell and Gene Therapy	**$2,482,241**
Anti-obesity	**$6,023,245**
Total	**$8,505,486**

Public and State-Owned Covered Entities:

Change	Estimated Cost
Cell and Gene Therapy	$1,723,809
Anti-obesity	$9,921,519
Total	$11,645,328
Percentage of claims attributable to Public Covered Entities	18%
Total Estimated Cost for Public Entities	$2,096,159
6-month impact for duration of Emergency Regulation	$1,048,079.50

IV. ASSUMPTIONS

Assumptions for both Cell and Gene Therapy and Anti-Obesity estimates

- The estimated increase in annual expenditures by Covered Entities will be offset by an equal increase in claims payment by MHD, resulting in no net change in profit for the Covered Entity. Savings to the state are realized through increased rebate revenue, which more than offset the increased reimbursement to the Covered Entities.
- Covered Entities bill MHD for 340B-purchased, non-physician-administered medications at the actual acquisition cost.
- Covered Entities have established processes for purchasing 340B and non-340B medications and billing MHD with the appropriate claim level identifier.
    - During SFY24, Covered Entities utilized non-340B stock for MHD participants 23.72% of the time based on paid claims history.
- MHD reimburses providers based on actual acquisition cost reimbursement methodology. If a Covered Entity purchases a medication outside of the 340B program, MHD will reimburse at the higher, non-340B rate, resulting in a higher expenditure by the Covered Entity and with a higher reimbursement by MHD.
- The supplemental rebate that the state would forgo for each 340B claim:
    - Based on the confidential and propriety nature of the supplemental rebate amounts, MHD utilized the overall weighted average of supplemental rebates for drugs from supplemental rebate agreements in place for April 1, 2024 – June 30, 2024, and actual utilization during the quarter, 32.2% of the total cost per claim.

- To calculate the anticipated impact to public facilities, MHD utilized percentage of 340B claims during SFY24 that were billed to MO HealthNet from public Covered Entities (18%)

Cell and Gene Therapy assumptions

- Covered Entities are purchasing cell and gene therapies at the ceiling price when purchased through the 340B program.
- Estimates are based on SFY2024 MHD paid claims data and pricing on the date of service.

Anti-Obesity assumptions

MHD does not currently cover drugs approved by the FDA for anti-obesity. MHD utilized the overall average federal rebate percentage to estimate the ceiling price paid by Covered Entities for anti-obesity agents. The federal rebate amounts are confidential and proprietary pursuant to Section 1927 of the Social Security Act (42 U.S.C. § 1396r-8). MHD calculated an anticipated fiscal impact based on the following:

- The estimated number of participants who would qualify for anti-obesity treatment.
- The current utilization of drugs with the same mechanism of action as the anti-obesity treatments.
- The anticipated percentage of participants who would seek treatment, based on a review of other State Medicaid Programs, discussions with MHD providers, and market analysis.
- The percentage of the participants who would receive the anti-obesity drug through a Covered Entity with 340B stock based on the percentage of overall MHD pharmacy claims that are billed as 340B stock by covered entities (10.57% during April 1, 2024 – June 30, 2024).
- Federal rebate to calculate the ceiling price for each 340B claim.
    - Based on the confidential and propriety nature of the federal rebate amounts, MHD utilized the overall average of federal rebates for drugs in place from April 1, 2024 to June 30, 2024, and actual utilization during the quarter, 53.04% of the total cost per claim.

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

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

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:
449	Covered Entities billing claims for 340B purchased medications	Six month estimated cost: $4,774,585 Annual estimated cost: $9,549,169

III. WORKSHEET

Cell and Gene Therapy Worksheet:

Number of cell and gene therapy claims billed to the MO HealthNet Division (MHD) during SFY24	101
Number of 340B purchased cell and gene therapy claims billed to MHD by Covered Entities during SFY24	3
The amount reimbursed for 340B purchased cell and gene therapy claims billed to MHD by Covered Entities during SFY24 (proxy for CE's actual acquisition cost)	$5,985,015
The amount that would have been reimbursed for the same claims had they not been purchased through the 340B program (proxy for CE's actual acquisition cost if not purchased through 340B program)	$7,708,824
The difference in actual acquisition cost for cell and gene therapy when utilizing non-340B stock compared to 340B stock	$1,723,809

Anti-Obesity Worksheet:

Anticipated Prescriptions for an Anti-obesity Agent for 1 year	170,000

Updated 03/19/2021

Average cost of claim for Anti-Obesity Agent	$1,041
Average Federal Rebate Percentage for all MHD Drug Claims	53.04%
Anticipated Percentage of Anti-Obesity Agents filled at 340B Covered Entities using 340B stock	10.57%
Increased purchase price of anti-obesity agents when utilizing non-340B compared to 340B (amount to be offset by increased MO HealthNet reimbursement)	$9,921,519

Change	Estimated Cost
Cell and Gene Therapy	$1,723,809
Anti-obesity	$9,921,519
Total	$11,645,328
Percentage of claims attributable to Private Covered Entities	82%
Total Estimated Cost for Private Entities	$9,549,169
6 month impact for the duration of Emergency Regulation	$4,774,585

IV. ASSUMPTIONS

Assumptions for both Cell and Gene Therapy and Anti-Obesity estimates

- The estimated increase in annual expenditures by Covered Entities will be offset by an equal increase in claims payment by MHD, resulting in no net change in profit for the Covered Entity. Savings to the state are realized through increased rebate revenue, which more than offsets the increased reimbursement to the Covered Entities.
- Covered Entities bill MO HealthNet for 340B-purchased, non-physician-administered medications at the actual acquisition cost.
- Covered Entities have established processes for purchasing 340B and non-340B medications and billing MHD with the appropriate claim level identifier.
    - During SFY24, Covered Entities utilized non-340B stock for MO HealthNet participants 23.72% of the time based on paid claims history.
- MHD reimburses providers based on actual acquisition cost reimbursement methodology. If a Covered Entity purchases a medication outside of the 340B program, MHD will reimburse at the higher, non-340B rate, resulting in a higher expenditure by the Covered Entity and a higher reimbursement by MHD.
- To calculate the anticipated impact to private facilities, MHD utilized percentage of 340B claims during SFY24 that were billed to MO HealthNet from private Covered Entities (82%)

Cell and Gene Therapy assumptions

- Covered Entities are purchasing cell and gene therapies at the ceiling price when purchasing through the 340B program.
- Estimates are based on SFY2024 MO HealthNet paid claims data.

Anti-Obesity assumptions
MO HealthNet (MHD) does not currently cover drugs approved by the FDA for anti-obesity. MHD utilized the overall average federal rebate percentage to estimate the ceiling price paid by Covered Entities for anti-obesity agents. The federal rebate amounts are confidential and proprietary pursuant to Section 1927 of the Social Security Act (42 U.S.C. § 1396r-8).
MHD calculated an anticipated fiscal impact based on the following:

- The estimated number of participants who would qualify for anti-obesity treatment.
- The current utilization of drugs with the same mechanism of action as the anti-obesity treatments.
- The anticipated percentage of participants who would seek treatment, based on a review of other State Medicaid Programs, discussions with MHD providers, and market analysis.
- The percentage of the participants who would receive the anti-obesity drug through a Covered Entity with 340B stock based on the percentage of overall MHD pharmacy claims that are billed as 340B stock by covered entities (10.57% during April 1, 2024 – June 30, 2024).
- Federal rebate to calculate the ceiling price for each 340B claim.
    - Based on the confidential and propriety nature of the federal rebate amounts, MHD utilized the overall average of federal rebates for drugs in place from April 1, 2024, to June 30, 2024, and actual utilization during the quarter, 53.04% of the total cost per claim.