Rule Impact Statement (2025)

A. Purpose of the proposed rule and legal authority *(75 OS § 253(B)(2)(b)(1), 75 OS 303(D)(2)(a))*

The proposed rule revisions seek to remove certain high-cost drugs and therapies from the 340B Drug Pricing Program, in order to control costs and preserve the integrity of the 340B program. The 340B program is a federal initiative that allows health care organizations to purchase certain drugs directly from pharmaceutical manufacturers at a discount.

Legal Authority: The Oklahoma Health Care Authority Act, Section 5007 (C)(2) of Title 63 of Oklahoma Statutes; The Oklahoma Health Care Authority Board; Section 340B of the Public Health Service Act; 42 CFR Part 10.

B. Brief description of the proposed rule *(75 OS 253(B)(2)(b)(3))*

The proposed revisions create a 340B Carve Out Drug list, consisting of cell and gene therapies, drugs currently under a value-based agreement, or Brand Preferred Drugs where the cost to the Medicaid program is $500,000 or higher, annually. Drugs on this list would be prohibited from being dispensed or administered to Oklahoma Medicaid members if purchased at 340B prices.

C. Classification of proposed rule *(75 OS 253(B)(2)(b)(2))*

Classification: ☐ Major ☒ Nonmajor

Justification: (Include estimate of total implementation and compliance costs over 5 years and basis for estimate. If ≥ $1,000,000 → classified as major.)

Total annual implementation and compliance costs: Based on projected implementation and compliance costs totaling $111,995.05 over five years, this rule is classified as Nonmajor.

Methodology used to calculate costs *(75 OS 253(B)(2)(b)(7)):* Costs and program changes are largely expected to be to be incurred by the OHCA primarily due to system changes to drug rebate subsystems that are estimated at 435 billable hours and $50,995.05 that is 25% state share ($12,748.76) and 75% federal share ($38,246.29). These changes ensure drugs listed on the 340B Carve Out Drug list are invoiced for all applicable federal and supplemental invoices. Maintenance of the 340B Carve Out Drug list, research associated with adding additional drugs to the list and related communications, is expected to have an estimated administrative cost of $9,600 annually, with an estimate of $13,000 for development and initial implementation. Provider compliance related to identification of 340B purchased drugs is the same as it is today so there is not additional cost to providers in this regard.

***D.* Description of affected classes of persons most likely to be impacted by the proposed rule** *(75 OS 253(B)(2)(b)(4), 75 OS 303(D)(2)(b))*

340B Providers dispensing, or administering, high-cost drugs may be impacted by inability to purchase these drugs at reduced prices.

E. Description of classes who will benefit from the proposed rule *(75 OS 253(B)(2)(b)(5), 75 OS 303(D)(2)(c))*

Controlling costs related to high-cost drug therapies will benefit members who need these products by protecting access to them, if uncontrolled costs due to widespread use incur higher costs to the Medicaid system.

F. Comprehensive economic impact analysis *(75 OS 253(B)(2)(b)(6), 75 OS 303(D)(2)(d))*
Methodology used to calculated costs *(75 OS 253(B)(2)(b)(7)):*

340B Providers will continue to bill SoonerCare, and SoonerSelect plans, as required today and will be reimbursed rates consistent with non 340B providers on drugs listed on the 340B Carve Out Drug list. The OHCA adjusts reimbursement by the 340B ceiling price, which is the regular rate minus federal rebate amount, on 340B purchased drug utilization on a quarterly basis to meet CMS' requirement of reimbursing at 340B ceiling price. While 340B providers will receive the full reimbursement amount on non 340B purchased drugs, the OHCA cannot know if these drugs are being purchased below the ceiling price from the manufacturers when purchased through the 340B program. There is some potential for revenue loss to 340B providers because of this but this is outweighed by preserving the negotiated net cost to the state when utilization does not include 340B purchased drug utilization. No additional FTEs are anticipated since these changes fit within the OHCA's existing framework for the 340B Drug Program. Implementation will be absorbed within existing staff capacity.

G. Probable costs and benefits to OHCA and other agencies *(75 OS 253(B)(2)(b)(6), 75 OS 303(D)(2)(e))*

Costs to OHCA are anticipated to be minimal, related primarily to analysis of drug costs and usage when considering placement of a product on the 340B Carve Out List. Benefits to OHCA include greater cost controls and preservation of access to high-cost drugs when needed.

H. Economic impact on political subdivisions and whether their cooperation is required *(75 OS 253(B)(2)(b)(8), 75 OS 303(D)(2)(f))*

No economic impact is anticipated. No cooperation from political subdivisions is required.

I. Economic impact on small businesses *(75 OS 253(B)(2)(b)(9), 75 OS 303 (D)(2)(g))*

Potential impact from no longer being able to purchase 340B Carve Out drugs at 340B prices, though the agency expects this to be offset by cost controls. Additionally, providers will receive reimbursement at regular rates consistent with non 340B providers for these carve out drugs. Reimbursement for utilization of 340B purchased drugs is adjusted to the 340B ceiling price which is essentially the regular rate minus the federal rebate amount.

J. Measures taken to minimize compliance costs and assessment of less costly, less intrusive, or nonregulatory alternatives *(75 OS 253(B)(2)(b)(10), 75 OS 303(D)(2)(h))*

In order to receive additional rebates from the federal CMMI CGT Access Model, Value Based Agreements, and standard supplemental rebate agreements, products must not be purchased at 340B prices. Alternative measures are not available but finalized language has been reviewed and revised to make clear cost savings associated with the rule change.

K. Effect of the rule on public health, safety, and the environment *(75 OS 253(B)(2)(b)(11), 75 OS 303(D)(2)(i))*

The proposed revisions are expected to benefit public health by controlling costs in the Medicaid program.

L. Detrimental effects if the proposed rule is not implemented *(75 OS 253(B)(2)(b)(12), 75 OS 303(D)(2)(j))*

There would be a financial impact due to loss of rebates associated with 340B purchased drugs where we see additional rebates when utilization is non 340B. There is potential for this loss to grow if utilization for drugs with supplemental rebates agreements in place increases at locations purchasing these drugs at 340B prices.

M. Summary of and preliminary comparison to existing or proposed federal regulations *(75 OS 303(D)(2)(n))*

No existing or proposed federal regulations similar to this are known at this time.

N. Analysis of alternatives to adopting the proposed rule *(75 OS 303(D)(2)(l))*

The alternative would be to allow drugs that are part of the CMMI CGT Access Model, Value Based Agreements and Brand Preferred Drugs where the cost to the Medicaid program is $500,000 annually, or higher, to be purchased at 340B prices which would make them ineligible for supplemental rebate collection. In 25Q2 supplemental and value based rebates made up 25% of the $200.9M in rebates collected. Supplemental rebates are a significant portion of the savings associated with drug rebate and not adopting this rule would prevent us from collecting additional rebates associated with high cost drugs; contributing to growing expenses.

O. Estimates of internal OHCA employee time and other resources used to develop the proposed rule *(75 OS 303(D)(2)(m))*

An estimated 325 hours between running reports, internal meetings within pharmacy to develop the rule revisions, correspondence with other states & researching their policies around this, developing requirements for system changes that may be needed, discussions with providers, initial permanent rule making cycle submission and the TMO process review and approval for second iteration.

P. Date statement prepared or modified *(75 OS 253(B)(2)(b)(13), 75 OS 303(D)(2)(k))*

Prepared: 12.3.2025
Modified: 12.29.2025