**Oklahoma Health Care Authority**

The Oklahoma Health Care Authority (OHCA) values your feedback and input. It is very important that you provide your comments regarding the proposed rule change by the comment due date. Comments can be submitted on the OHCA's Proposed Changes Blog.

**OHCA COMMENT DUE DATE:** January 6, 2025

The proposed policy is a Permanent Rule. The proposal was presented at the Tribal Consultation held on November 5, 2024. Additionally, this proposal will be presented at a Public Hearing scheduled for January 6, 2025, and is scheduled to be presented as permanent rules to the OHCA Board of Directors on January 15, 2025.

**SUMMARY:** The proposed revisions seek to remove certain drugs and therapies from the 340b Drug Pricing Program. The 340b program is a federal initiative that allows health care organizations to purchase certain drugs at a discount direct from pharmaceutical manufacturers. One restriction on this program is that no rebates can be collected from any drug or therapy purchased under the program, including supplemental rebates. These revisions would prohibit purchasing drugs which are in a supplemental rebate agreement from being purchased under the 340b program.

**LEGAL AUTHORITY**
The Oklahoma Health Care Authority Act, Section 5007 (C)(2) of Title 63 of Oklahoma Statutes; the Oklahoma Health Care Authority Board

**RULE IMPACT STATEMENT:**

**STATE OF OKLAHOMA**
**OKLAHOMA HEALTH CARE AUTHORITY**

SUBJECT: Rule Impact Statement
APA WF # 24-32

A. Brief description of the purpose of the rule:

The proposed revisions seek to remove certain drugs and therapies from the 340b Drug Pricing Program. The 340b program is a federal initiative that allows health care organizations to purchase certain drugs at a discount direct from pharmaceutical manufacturers. One restriction on this program is that no rebates can be collected from any drug or therapy purchased under the program, including supplemental rebates. These revisions would prohibit purchasing drugs which are in a supplemental rebate agreement from being purchased under the 340b program.

B. A description of the classes of persons who most likely will be affected by the proposed rule, including classes that will bear the cost of the proposed rule, and any information on cost impacts received by the agency from any private or public entities:

The proposed rule changes may affect some providers who currently purchase pharmaceuticals direct from manufacturers through the 340b program, if those products are also covered under a supplemental rebate agreement with OHCA.

C. A description of the classes of persons who will benefit from the proposed rule:

Potential cost savings to the agency may provide a benefit to any SoonerCare member.

D. A description of the probable economic impact of the proposed rule upon the affected classes of persons or political subdivisions, including a listing of all fee changes and, whenever possible, a separate justification for each fee change:

There is no probable economic impact and there are no fee changes associated with the rule change for the above classes of persons or any political subdivisions.

E. The probable costs and benefits to the agency and to any other agency of the implementation and enforcement of the proposed rule, the source of revenue to be used for implementation and enforcement of the proposed rule, and any anticipated affect on state revenues, including a projected net loss or gain in such revenues if it can be projected by the agency:

The proposed rule is budget neutral, with potential positive impact due to rebate collections.

F. A determination of whether implementation of the proposed rule will have an economic impact on any political subdivisions or require their cooperation in implementing or enforcing the rule:

The proposed rule changes will not have an economic impact on any political subdivision or require their cooperation in implementing or enforcing the rule changes.

G. A determination of whether implementation of the proposed rule will have an adverse effect on small business as provided by the Oklahoma Small Business Regulatory Flexibility Act:

The agency does not anticipate that the proposed rule changes will have an adverse effect on small businesses.

H. An explanation of the measures the agency has taken to minimize compliance costs and a determination of whether there are less costly or non-regulatory methods or less intrusive methods for achieving the purpose of the proposed rule:

The agency has taken measures to determine that there are no other legal methods to achieve the purpose of the proposed rule. Measures included a formal public comment period and tribal consultation.

I. A determination of the effect of the proposed rule on the public health, safety and environment and, if the proposed rule is designed to reduce significant risks to the public health, safety and environment, an explanation of the nature of the risk and to what extent the proposed rule will reduce the risk:

The proposed rule should have no adverse effect on the public health, safety or environment.

J. A determination of any detrimental effect on the public health, safety and environment if the proposed rule is not implemented:

The agency does not anticipate any detrimental effect on the public health and safety if the proposed rule is not passed.

K. The date the rule impact statement was prepared and if modified, the date modified:

Prepared date: November 22, 2024

**RULE TEXT:**

**TITLE 317. OKLAHOMA HEALTH CARE AUTHORITY**
**CHAPTER 30. MEDICAL PROVIDERS-FEE FOR SERVICE**

**SUBCHAPTER 5. INDIVIDUAL PROVIDERS AND SPECIALTIES**

**PART 7. PHARMACIES**

**317:30-5-87. 340B Drug Discount Program**

(a) The 340B Drug Discount Program is a drug-pricing program established under section 256b of Title 42 of the United States Code (U.S.C) under which a manufacturer of covered outpatient drugs agrees that it will not charge a 340B covered entity more than the 340B price for a 340B covered outpatient drug.
(b) Covered entities participating in the 340B Drug Discount Program will adhere to the following provisions outlined in this Section and as defined in 42 U.S.C. §256b. Covered entities must:

(1) Notify the OHCA Pharmacy Department in writing within thirty (30) days of any changes in 340B Program participation, as well as any changes in name, address, National Provider Identification (NPI), SoonerCare Provider Number, etc.
(2) Maintain their status on the Health Resources & Services Administration (HRSA) Medicaid Exclusion File (MEF) and report any changes to the OHCA within thirty (30) days.
(3) Execute a contract addendum with the OHCA in addition to their provider contract.
(4) Drugs designated by OHCA as 340B Carve Out Drugs shall be prohibited from being dispensed or administered to Oklahoma Medicaid members if purchased at 340B prices. Any drugs designated by OHCA as 340B Carve Out Drugs will be posted on the agency website at www.oklahoma.gov/ohca.

(c) To prevent a duplicate discount, quarterly adjustments will be made to all pharmacy or medical claims for drugs submitted by covered entities when billed using the registered SoonerCare Provider Number on the MEF.

(1) All pharmacy claims submitted by covered entities shall be adjusted by the 340B ceiling price whether purchased through the 340B Program or otherwise.

(2) Medical claims submitted by covered entities with procedure code modifiers indicating the use of the 340B purchased drugs shall be adjusted by the 340B ceiling price. OHCA will adjust each claim by subtracting the 340B ceiling price from the amount reimbursed and multiplying the difference by the quantity submitted. OHCA will use the 340B ceiling price applicable to the quarter in which the claim is paid. Medical claims submitted by covered entities with a procedure code modifier indicating the use of non 340B purchased drugs will not be adjusted by the 340B ceiling price and will be submitted for federal rebates as required by CMS. Covered entities are required to use an appropriate procedure code modifier on all physician administered drug lines when submitting medical claims.

(3) If a 340B covered entity fails to pay quarterly adjustments invoiced by OHCA within forty-five (45) days of receipt, it may result in a debt to the State of Oklahoma subject to applicable interest pursuant to prompt payment methodology at OAC 260:10-3-3.

(4) The quarterly adjustments invoiced, including applicable interest, must be paid regardless of any disputes made by the covered entity. If a covered entity fails to pay OHCA the adjustments invoiced within forty-five (45) days of receipt, the adjustments invoiced and applicable interest will be deducted from the facility's payment.

(d) Contract pharmacies for covered entities may be permitted to bill drug products purchased under the 340B Drug Discount Program to the Oklahoma Medicaid Program when certain conditions are met and an agreement is in place between the OHCA, the contract pharmacy, and the covered entity. These pharmacies will be subject to the recovery process stated in this Section.