## **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 2, 2024

The proposed policy changes are Permanent Rules. The proposed policy changes were presented at the Tribal Consultation held on October 31, 2023. The proposed rule changes will be presented at a Public Hearing on January 8, 2024. Additionally, this proposal is scheduled to be presented to the Medical Advisory Committee on January 4, 2024 and the OHCA Board of Directors on January 17, 2024.

#### **REFERENCE: APA WF 23-26**

#### **SUMMARY:**

**340B Non-Compliant Providers** - The proposed revisions ensure OHCA has mechanisms in place to preserve the net cost on prescription drug services through the current 340B Shared Savings model. The revisions institute a 45-day due date from receipt of invoice, a monetary penalty/interest for paying after the due date (modeled on the methodology used in Prompt Payment Rules promulgated by OMES, OAC 260:10-3-3), and the ability to withhold payment from facilities that are non-compliant in order to receive the unpaid invoice amounts.

#### **LEGAL AUTHORITY:**

The Oklahoma Health Care Authority Act, Section 5007 (C)(2) of Title 63 of Oklahoma Statutes; The Oklahoma Health Care Authority Board; 42 CFR Part 10

#### **RULE IMPACT STATEMENT:**

## STATE OF OKLAHOMA OKLAHOMA HEALTH CARE AUTHORITY

SUBJECT: Rule Impact Statement

APA WF # 23-26

## A. Brief description of the purpose of the rule:

The purpose of the rule is to ensure OHCA has mechanisms in place to preserve the net cost on prescription drug services through the current 340B Shared Savings model. Recently, some providers are not paying quarterly invoices in a timely fashion. Some of these invoices are for amounts as high as \$4M. Further, when 340B drugs are utilized, those drugs are not claimed on supplemental invoices to manufacturers. OHCA is then limited to collecting the equivalent of the federal rebates due for a drug from the provider. The rule change would ensure providers are fulfilling their responsibilities in participating in the 340B Shared Savings Program.

The proposed revisions institute a 45-day due date from receipt of invoice, a monetary penalty/interest for paying after the due date (pursuant to the Prompt Payment methodology in OAC 260:10-3-3), and the ability to withhold payment from facilities that are non-compliant in order to receive the unpaid invoiced amounts.

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:

Providers in the 340B Shared Savings program will be impacted as there will be an enforcement mechanism to ensure compliance with program requirements. This rule should not place any cost burden on public or private entities. No information on any cost impacts were received from any entity.

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

The proposed rule changes will benefit SoonerCare members in general and members relying on prescription drug benefits in particular by streamlining payments from providers in the 340B Shared Savings Program.

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

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 effect on state revenues, including a projected net loss or gain in such revenues if it can be projected by the agency:

Agency staff has determined that the proposed rule changes are budget neutral.

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 will not have an economic impact on any political subdivisions or require their cooperation in implementing or enforcing the rule.

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 proposed rule will not have an adverse effect on small businesses as provided by the Oklahoma Small Business Regulatory Flexibility Act.

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 is no less costly or non-regulatory method or less intrusive method for achieving the purpose of the proposed rule.

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 effect on the public health, safety, and 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, safety, or environment if the proposed rule changes are not implemented.

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

Prepared: October 19, 2023 Modified: December 27, 2023

#### RULE TEXT

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

## SUBCHAPTER 5. INDIVIDUAL PROVIDERS AND SPECIALTIES

## **PART 5. 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. \( \frac{1}{2} \) 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.
- (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.