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 18, 2022

The proposed policy change is a Permanent Rule. The proposed policy was presented at the November 2, 2021 Tribal Consultation. The proposed rule change will be presented at a Public Hearing on January 18, 2022. Additionally, this proposal is scheduled to be presented to the Medical Advisory Committee on January 13, 2022 and to the OHCA Board of Directors on January 19, 2022.

Reference: APA WF # 21-33

SUMMARY:

Improve 340B Shared Savings Methodology — The proposed revisions will modify existing rules and the State Plan to improve the identification of 340B drugs and non 340B drug purchases. These revisions will require providers to bill the Agency with a procedure code modifier, on outpatient and hospital claims, that will identify a 340B drug from a non 340B drug. Additional revisions will adjust the methodology by which Medicare crossover claims are included on drug rebate invoices to 340B providers.

LEGAL AUTHORITY

The Oklahoma Health Care Authority Act, Section 5007 of Title 63 of Oklahoma Statutes; the Oklahoma Health Care Authority Board; Section 256b of Title 42 of the United States Code

RULE IMPACT STATEMENT:

STATE OF OKLAHOMA
OKLAHOMA HEALTH CARE AUTHORITY

SUBJECT: Rule Impact Statement
APA WF # 21-33

A. Brief description of the purpose of the rule:

The proposed revisions will improve the identification of 340B drugs and non 340B drug purchases. These revisions will require providers to bill the Agency with a procedure code modifier, on outpatient and hospital claims, that will identify a 340B drug

from a non 340B drug. Additional revisions will adjust the methodology by which Medicare crossover claims are included on drug rebate invoices to 340B providers.

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:

340B covered entities will most likely be affected by the new requirement to report new procedure code modifiers to differentiate 340B drugs from non 340B drugs on outpatient and hospital claims.

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

The proposed rule changes will benefit 340B covered entities and the OHCA by appropriately identifying and reimbursing 340B drugs as required by federal law.

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 impact of the proposed rule upon any classes of persons or 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 effect on state revenues, including a projected net loss or gain in such revenues if it can be projected by the agency:

The proposed rule changes can potentially result in a reduction to the Agency's overall revenue collections. The potential combined federal and state revenue total loss is $3,070,428; with $1,002,188 in state share for SFY2023.

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:

There is no economic impact on political subdivisions.

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 business.

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 a positive 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 25, 2021
Modified: December 1, 2021

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 purpose of this Section is to provide special provisions for providers participating in the 340B Drug Discount program. The 340B Drug Discount program special provisions apply to a provider that has asserted it is a "covered entity" or a contract pharmacy for a covered entity under the provisions of 42 U.S.C. § 256b of the United States Code (otherwise known as the 340B Drug Discount Program).~~

~~(b) Covered Entities.~~

~~(1) The covered entity must notify OHCA in writing within 30 days of any changes in 340B participation, as well as any changes in name, address, NPI number, etc.~~

~~(2) The covered entity must maintain their status on the HRSA Medicaid exclusion file and report any changes to OHCA within 30 days.~~

~~(3) The covered entity must execute a contract addendum with OHCA in addition to their provider contract.~~

~~(4) To prevent a duplicate discount, quarterly adjustments will be made to all pharmacy or medical claims for drugs submitted by the covered entity. OHCA will adjust each claim by subtracting the 340B Ceiling Price from the amount reimbursed and multiplying the difference by the quantity submitted. All drugs shall be adjusted by the 340B Ceiling Price whether purchased through the 340B program or otherwise when billed using the registered SoonerCare NPI number on the HRSA Medicaid Exclusion File. OHCA will use the 340B Ceiling Price applicable to the quarter in which the claim is paid.~~

~~(c) 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 OHCA, the contract pharmacy and the covered entity. These pharmacies will be subject to the recovery process stated above.~~

(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) 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 NPI 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.

(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.