340B Policy and Procedures Manual

Outpatient Drugs and Physician Administered Drugs

Effective: **April 1, 2020**

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I. Purpose

This document contains the Kentucky Medicaid policies and procedures for Managed Care Organization (MCO) and Fee-for-Service (FFS) providers who participate in the 340B Drug Pricing Program. This guidance is issued to comply with federal law regarding the 340B Drug Pricing Program (42 U.S.C. 256b). This manual applies to prescription drugs billed at pharmacy point-of-sale or on the CMS 1500/837P.

II. Summary

The overlap of the 340B Drug Pricing Program and the Medicaid Drug Rebate Program creates the possibility of duplicate discounts, which are prohibited under federal law.

States are federally mandated to seek federal drug rebates on MCO claims, meaning that the potential for duplicate discounts exists for managed care claims.

Kentucky DMS utilizes the Health Resources and Services Administration's (HRSA) Medicaid Exclusion File for both Fee-for-Service and Managed Care Organization claims in order to prevent duplicate discounts.

III. 340B & Drug Rebate Program Background

The national Medicaid Drug Rebate Program was established in 1991 as a means to offset both state and federal Medicaid drug expenditures. When a drug manufacturer enters into a national rebate agreement, they are also required to enter into agreements with the 340B Drug Pricing Program.

The 340B Drug Pricing Program was designed to enable participating providers, referred to as "covered entities," to stretch scarce federal resources by obtaining covered outpatient drugs at significantly discounted prices. This program is administered by HRSA's Office of Pharmacy Affairs (OPA).

When a covered entity bills Medicaid for a pharmacy or outpatient physician-administered drug, the possibility of duplicate discounts exists due to the overlap of the Medicaid Drug Rebate and 340B Drug Pricing Programs. Therefore, when a covered entity enrolls in the 340B program, it must choose whether it will "carve-in" or "carve-out" its Medicaid FFS and MCO patients, respectively. Carve-in means that all drugs dispensed to Medicaid patients were purchased under the 340B Drug Pricing Program, while carve-out means that drugs dispensed to Medicaid patients were not purchased under the 340B Drug Pricing Program.

Additional information on the 340B Drug Pricing Program can be found at http://www.hrsa.gov/opa.

IV. Medicaid Exclusion File

HRSA communicates carve-in designations to states via the Medicaid Exclusion File (MEF) in order to alert states that Medicaid Drug Rebates should not be sought on MEF providers' drug claims.

When a covered entity chooses to carve-in, it must provide HRSA with the National Provider Identification (NPI) and/or Medicaid provider number for each site that carves in for the purpose of

inclusion in the MEF. An entry in the MEF indicates that a covered entity has chosen to carve-in for a single quarter.

A covered entity can change its carve-in or carve-out designation at any time; however, HRSA stipulates that the effective date of any such change will be the first day of a calendar quarter. Status changes for the next calendar quarter must be provided by the 15th day of the month preceding the quarter's start (March 15, June 15, Sep. 15 and Dec. 15). Changes submitted after this date will not be effective until the start of the second quarter following the change. Because the MEF is produced on the 15th day of the month preceding a quarter's start, this ensures that an entity's carve-in or carve-out election is properly reflected on the applicable quarter's MEF.

States can elect to identify 340B claims using methods other than the exclusion file (e.g. claim level indicators).

Additional information regarding the MEF can be found at https://opanet.hrsa.gov/340B.

V. Managed Care Organizations

Section 2501(c) of the Patient Protection and Affordable Care Act (ACA) requires state Medicaid agencies to seek rebates on drugs dispensed by Medicaid Managed Care Organizations. This means that the potential for duplicate discounts exists for both FFS and MCOs.

Due to this duplicate discount potential, if a covered entity appears on the MEF, Kentucky will exclude that provider's FFS and MCO claims from rebate invoicing. Since claims for FFS Medicaid and MCO Medicaid recipients are treated identically in regards to exclusion from rebate invoicing.

VI. Fee-for-Service: Contract Pharmacies

Contract pharmacies may not submit claims to Medicaid FFS for 340B-acquired drugs. A 340B contract pharmacy **must carve out** Medicaid FFS from its 340B operation. This verbiage is found in both the Kentucky State Plan Amendment (SPA) KY-17-00 and the Kentucky Administrative Regulation 907 KAR 23:020.

KY-17-001: Drugs acquired through the 340B Program and dispensed by 340B contract pharmacies are not covered.

907 KAR 23:020 Section 4 (6) (c): A drug dispensed by a 340B contract pharmacy shall not be eligible as a 340B transaction and shall be reimbursed in accordance with the lowest of logic as required by Section 2 of this administrative regulation plus the professional dispensing fee.

VII. Managed Care Organization: Contract Pharmacies

Contract pharmacies may submit claims to Medicaid MCO for 340B-acquired drugs, with the required 340B claim level identifiers.

VIII. Kentucky Medicaid Fee-for-Service NCPDP D.0 Billing Changes for 340B Outpatient Drug Claims

Effective **April 1, 2020**, Kentucky's Department for Medicaid Services will not collect rebates for all fee-for-service and managed care 340B claims submitted via the National Council for Prescription Drug Programs (NCPDP) D.0 format with the following:

- Value of "20" in field 420-DK, Submission Clarification Code

Providers are responsible for correctly identifying claims dispensed with 340B purchased drugs and to ensure rebates are not collected. Providers shall submit both FFS and MCO claims with the following claim-level indicators below.

Pharmacy Claims:

NCPDP Field	NCPDP Field Name	NCPDP Values
420-DK	Submission Clarification Code	20 = 340B

Physician-Administered Drug Claims:

Providers shall submit the **UD modifier** to identify 340B drugs on outpatient physician-administered drug claims. This includes outpatient hospital and outpatient professional service 340B drug claims.

- CMS 1500: Field Number: 24D Field Value: Procedures, Services, or Supplies Field Description: CPT/HCPCS & Modifier.
- 837P: Enter HCPCS code in Loop 2400 SV101-2 followed by the modifier UD. Example: J1111 billed as J1111UD.

For any physician-administered drugs not purchased through the 340B program, no code modifier is required.

IX. Additional Guidance

FAQS on the 340B program itself, as well as information on how to ask additional questions, can be found on the HRSA website.