

## General Comments to Proposed Manual

Kentucky Department for Medical Services (DMS) received the following comments and our response follows:

**Comment:** The proposed manual appears to fall within the definition of an “administrative regulation” which is required to be promulgated in accordance with Kentucky’s Administrative Procedures Act.

**Response:** The proposed manual does not modify a statute or administrative regulation; expand upon or limit a statute or administrative regulation; or except as authorized by the Constitution of the United States, the Constitution of Kentucky, or a statute, expand or limit a right guaranteed by the Constitution of the United States, the Constitution of Kentucky, a statute, or an administrative regulation; therefore it is not required to be promulgated in accordance with Kentucky’s Administrative Procedures Act. See, KY. Rev. Stat. § 13A.130.

**Comment:** The proposed manual appears to require that DMS submit a State Plan Amendment (SPA) to the Centers for Medicare and Medicaid Services (CMS) because it will change the program policies and operational approach.

**Response:** DMS has reached out to CMS on this issue and clarity has been provided that a SPA is not necessary for any changes to MCO reporting requirements and can go in the state’s Provider Manual.

**Comment:** The proposed manual prohibits 340B Program-eligible providers from their right to choose whether or not they carve-in or carve-out Medicaid FFS and MCO prescriptions.

**Response:** Covered entities are still able to carve-in or carve-out Medicaid FFS or MCO, respectively. To clarify the language has been updated to, “Therefore, when a covered entity enrolls in the 340B program, it must choose whether it will “carve-in” or “carve-out” its 340B drugs for Medicaid FFS and MCO patients, respectively. Carve-in means that 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.”

**Comment:** The proposed manual appears to have been drafted without DMS performing or engaging in any research, study, or fact gathering processes to determine the manual’s impact.

**Response:** DMS has conducted outreach to various stakeholders culminating in the proposed policy and feedback period. This includes CMS, multiple state Medicaid agencies, and the provider community.

**Comment:** DMS has not provided a formal public procedure by which affected persons and entities may comment on the manual nor a sufficient time in which the public may comment.

**Response:** Formal public procedure was not required for the proposed manual. DMS allowed 62 days for public comment.

**Comment:** Covered entities cannot comply with HRSA requirements to change its carve-in or carve-out designation due to the timing of the proposed manual and the effective date.

**Response:** To allow covered entities ample time to change its carve-in or carve-out designation with HRSA, DMS is providing a grace period for covered entities for changes made in the proposed manual. The proposed policy was released on August 2, 2019 with an initial effective date of October 1, 2019.

This was changed to an effective date of the final manual to January 1, 2020. 340B covered entities are encouraged to begin submitting 340B claim level identifiers on January 1, 2020 when a 340B purchased drug is dispensed or administered to patients; however, the effective date of the policy will begin on April 1, 2020.

**Comment:** Concern on the timing of implementation, stating the January 1, 2020 deadline would not be possible.

**Response:** DMS is providing a grace period for covered entities for changes made in the proposed manual. Beginning January 1, 2020, DMS will accept claims with the claim level identifiers with a final policy effective date of April 1, 2020.

#### I. Purpose

DMS received the following comments and our response follows:

**Comment:** Ambiguity in the Purpose statement.

**Response:** The purpose statement has been updated to provide additional clarification, “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 340B drugs billed at pharmacy point-of-sale or on the CMS 1500/837P.”

#### II. Summary

DMS received the following comments and our response follows:

**Comment:** The proposed manual fails to acknowledge that state Medicaid agencies cannot collect rebates on 340B-eligible drugs billed through MCO programs.

**Response:** To prevent rebate collection on 340B-eligible drugs billed through MCO programs, the claim must be identified by either Submission Clarification Code 20 or the UD modifier.

**Comment:** The proposed manual should be updated to reflect that the Medicaid Exclusion File is only applicable to FFS claims.

**Response:** Kentucky DMS utilizes the Health Resources and Services Administration’s (HRSA) Medicaid Exclusion File (MEF) for both FFS and MCO claims in order to prevent duplicate discounts. The purpose of the proposed manual is to correct the aforementioned by utilizing claim level identification due to guidance from HHS.

**Comment:** Clarification as to whether DMS will no longer use the MEF and only employ the new method as explained in section VII.

**Response:** Beginning April 1, 2020, DMS will no longer utilize the MEF for MCO claims regardless of point-of-sale and will require claim level identifiers for all drugs purchased through the 340B Program and billed to Medicaid.

### III. 340B & Drug Rebate Program Background

DMS received the following comments and our response follows:

**Comment:** The proposed manual misstates the purpose of the 340B Program as though the 340B Program was intended to offset State and Federal Medicaid drug expenditures.

**Response:** DMS believes the language in the proposed manual states clearly the difference in the Medicaid Drug Rebate Program and the 340B Drug Pricing Program. 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 discounted prices. This program is administered by HRSA’s Office of Pharmacy Affairs (OPA).

**Comment:** The proposed manual effectively requires 340B covered entities to carve-out any 340B Program-eligible medication dispensed through a contract pharmacy.

**Response:** Covered entities are still able to carve-in or carve-out Medicaid FFS or MCO, respectively. To clarify the language has been updated to, “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.”

### IV. Medicaid Exclusion File

DMS received the following comments and our response follows:

**Comment:** Covered entities could not comply with HRSA requirements to change its carve-in or carve-out designation due to the timing of the proposed manual and the effective date.

**Response:** DMS is providing a grace period for covered entities for changes made in the proposed manual. Beginning January 1, 2020, DMS will accept claims with the claim level identifiers with a final policy effective date of April 1, 2020.

### V. Managed Care Organizations

DMS received the following comments and our response follows:

**Comment:** The proposed manual appears to indicate that all 340B Program-eligible claims, regardless of setting, will be excluded from DMS’s rebate invoicing.

**Response:** As mentioned previously, this manual applies to all 340B purchased drugs billed at pharmacy point-of-sale or on the CMS 1500/837P.

**Comment:** Without contractual provisions obligating MCOs to perform these functions, it appears that DMS cannot enforce the terms of the Proposed Manual against MCOs.

**Response:** The MCO contract states, “The contractor shall support all Department based efforts and initiatives for 340B claim identification at a claim level of detail, including utilization of the NCPDP fields designed for this purpose. Contractor shall require pharmacy Providers or processing vendors to identify 340B purchased drugs on claims in accordance with Department requirements.”

#### **VI. Fee-for-Service: Contract Pharmacies**

DMS received the following comments and our response follows:

**Comment:** Current Kentucky Medicaid FFS regulations do not acknowledge that HRSA permits contract pharmacies to bill 340B claims to Kentucky Medicaid FFS programs provided there is an arrangement between the covered entity, the contract pharmacy, and DMS.

**Response:** Kentucky Regulation (907 KAR 23:020 Section 4 (6) (c)) states: 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.

**Comment:** It is unclear with Kentucky DMS proceeded with the proposed manual without submitting it through the SPA process and Kentucky Administrative Procedures Act requirements.

**Response:** The proposed manual does not modify a statute or administrative regulation; expand upon or limit a statute or administrative regulation; or Except as authorized by the Constitution of the United States, the Constitution of Kentucky, or a statute, expand or limit a right guaranteed by the Constitution of the United States, the Constitution of Kentucky, a statute, or an administrative regulation; therefore it is not required to be promulgated in accordance with Kentucky’s Administrative Procedures Act. See, KY. Rev. Stat. § 13A.130. Additionally, DMS has reached out to CMS on this issue and clarity has been provided that a SPA is not necessary for any changes to MCO reporting requirements and can go in the state’s Provider Manual.

#### **VII. Managed Care Organization: Contract Pharmacies**

DMS received the following comments and our response follows:

**Comment:** An agreement in place with the State, the covered entity, and the contract pharmacy is unnecessary and against federal regulation and guidance. Comments also noted the absence of a template.

**Response:** In lieu of any contractual agreements with DMS, DMS will post on the Cabinet for Health and Family Services Department for Medicaid Services Pharmacy web page a “Kentucky DMS 340B Procedures” document which will be applicable for all covered entities and contract pharmacies to ensure the state does not collect a rebate on any 340B purchased drugs. This document may be presented to HRSA for any audits effective April 1, 2020.

**Comment:** Concern that the proposed manual limits contract pharmacies to be within thirty (30) miles of the registered covered entity.

**Response:** DMS has removed this requirement from the final manual.

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

DMS received the following comments and our response follows:

**Comment:** Prospectively identifying 340B claims is difficult at point-of-sale.

**Response:** While Kentucky DMS's expectation is to have as many 340B claims as possible identified prospectively in real-time; if the claim is not identified as 340B eligible until after the fact, the pharmacy can reverse and resubmit the claim with the Submission Clarification Code of 20. This must be done within timely filing limits, as defined by the Kentucky Medicaid Pharmacy Provider Billing Manual ([https://kyportal.magellanmedicaid.com/public/client/static/kentucky/documents/KY\\_Provider\\_Manual.pdf](https://kyportal.magellanmedicaid.com/public/client/static/kentucky/documents/KY_Provider_Manual.pdf)). If the claim was prospectively identified as 340B eligible and it is later deemed ineligible, the pharmacy can reverse and resubmit the claim without the Submission Clarification Code of 20.

**Comment:** Moving to a retrospective claim identification models like states such as Oregon, New York, or Texas.

**Response:** DMS has conducted outreach to various stakeholders culminating in the proposed policy and feedback period. This includes CMS, multiple state Medicaid agencies, and the provider community. We also discussed this approach with multiple rebate vendors servicing Kentucky and other states. Moving to a retrospective model was evaluated, along with other approaches.

**Comment:** Adequate research had not been done to ensure Kentucky-resident pharmacies have sufficient infrastructure to comply with the proposed billing clarification code.

**Response:** All software issues with contract pharmacies are to be resolved by the covered entity and the pharmacy. DMS is not building the Submission Clarification Code, it is NCPDP standard, and is already required in specific circumstances. Refer to Kentucky D.0 Payer Specifications document ([https://kyportal.magellanmedicaid.com/public/client/static/kentucky/documents/KY-Billing\\_PayerSpecD0-20151104.pdf](https://kyportal.magellanmedicaid.com/public/client/static/kentucky/documents/KY-Billing_PayerSpecD0-20151104.pdf)). DMS is providing a grace period for covered entities for changes made in the proposed manual. Beginning January 1, 2020, DMS will accept claims with the claim level identifiers with a final policy effective date of April 1, 2020.

**Comment:** The discrepancy between the purpose section and the physician-administered drug claims section.

**Response:** The purpose statement has been updated to provide additional clarification, "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 340B drugs billed at pharmacy point-of-sale or on the CMS 1500/837P." The UD modifier will be required as noted in section VIII of the manual.