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CENTERS FOR MEDICARE & MEDICAID SERVICES
CENTER FOR MEDICAID & CHIP SERVICES

CMCS Informational Bulletin

DATE: January 8, 2020

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SUBJECT: Best Practices for Avoiding 340B Duplicate Discounts in Medicaid

The purpose of this Informational Bulletin is to outline a number of best practices that states are encouraged to consider to avoid billing manufacturers for Medicaid rebates (also known as receiving a "duplicate discount") for covered outpatient drugs purchased under the 340B Drug Pricing Program (340B Program). This guidance was also developed in response to two OIG reports which encouraged CMS to inform states about ways they could identify claims for 340B drugs to, in part, avoid duplicate discounts and enhance state compliance in this program.[1] [2]

State Medicaid agencies (states) are prohibited from billing manufacturers for Medicaid rebates for drugs dispensed to Medicaid patients that have already been discounted under the 340B Program. Stakeholders, including states, have indicated that avoiding duplicate discount billing has become more complex due to the increase in the number of Medicaid managed care beneficiaries as well as the number of prescriptions filled at 340B-entity contract pharmacies.

The Centers for Medicare & Medicaid Services (CMS) and the Health Resources & Services Administration (HRSA) continue to discuss concerns and potential solutions raised by stakeholders to avoid duplicate discount billing. This bulletin highlights several best practices for states to presently consider to avoid billing manufacturers for rebates for covered outpatient drugs purchased under the 340B Program.

Background

Section 340B(a)(5)(A) (the PHS Act) prohibits duplicate discounts; that is, manufacturers are not required to both provide a 340B price and pay the state a rebate under the Medicaid drug rebate program for the same drug. To help achieve this end, HRSA established the Medicaid Exclusion File (MEF) for Medicaid fee-for-service (FFS) claims as the mechanism to assist 340B covered entities, states and manufacturers in avoiding duplicate discounts.[3] The establishment of this MEF by HRSA satisfied the requirement at section 1927(a)(5)(C) of the Social Security Act to establish an alternative mechanism to ensure against duplicate discounts or rebates, if one was not established as required under that provision.

1 https://oig.hhs.gov/oei/reports/oei-05-09-00321.pdf
2 https://oig.hhs.gov/oei/reports/oei-05-14-00430.asp
3 https://340bopais.hrsa.gov/medicaidexclusionfiles

Two recent CMS rules included requirements relating to streamlining the interaction between Medicaid and the 340B Program with the goal of reducing duplicate discounts. On February 1, 2016, CMS published the Covered Outpatient Drugs final rule with comment period (CMS-2345-FC) (Final Rule) in the Federal Register. This Final Rule discussed that states are not responsible for submitting claims to manufacturers for rebates for drugs acquired under the 340B program.

On May 6, 2016, CMS published the Medicaid and CHIP Managed Care final rule (CMS-2390-F) (MC Final Rule), which included the state contracting requirements for Medicaid managed care organizations (MCOs), prepaid inpatient health plans, and prepaid ambulatory health plans (collectively referred to as Medicaid managed care plans) that provide covered outpatient drugs. That MC Final Rule established a requirement that states include a provision in all managed care plan contracts requiring that the managed care plans have procedures in place to exclude utilization associated with 340B drugs when states do not require submission of managed care drug claims data from covered entities directly, so that manufacturers will not be billed erroneously for rebates on 340B purchased drugs dispensed to Medicaid beneficiaries. See 42 CFR §438.3(s)(3).

The following sections outline best practices that state Medicaid programs may consider if facing challenges with avoiding billing for duplicate discounts.

Using the 340B Medicaid Exclusion File (MEF)

When covered entities enroll with HRSA to participate in the 340B Program, they must determine whether they will use 340B drugs for their Medicaid FFS patients ("carve-in") or whether they will purchase drugs for these beneficiaries through other mechanisms ("carve-out"). Covered entities are required to inform HRSA at the time they enroll in the 340B Program if they will purchase and dispense 340B drugs for their "carve-in" beneficiaries by providing their National Provider Identification (NPI) numbers and/or Medicaid billing number.[4]

Section 340B(a)(5)(A)(ii) of the PHS Act requires the Secretary of the Department of Health and Human Services (HHS) to establish a mechanism to ensure covered entities comply with the prohibition against billing for duplicate discounts. HRSA and CMS collaborated to establish the 340B Program MEF, which serves as the official data source to determine whether covered entities have opted to bill 340B drugs under Medicaid FFS. The MEF contains a listing of those covered entities that have opted to use drugs purchased through the 340B Program for "carve-in" beneficiaries, and have agreed to bill Medicaid accordingly, along with their corresponding NPI numbers and/or Medicaid Provider Numbers.

By referring to the MEF, states can more easily exclude Medicaid FFS drug claims from these covered entities when submitting Medicaid rebate requests to manufacturers. States are encouraged to use the MEF to help prevent duplicate discounts in Medicaid FFS. However, it is

[4] https://www.hrsa.gov/sites/default/files/opa/programrequirements/policyreleases/medicaidexclusionclarification020713.pdf

important to note that the MEF does not apply to 340B covered entities' arrangements with Medicaid managed care plans at this time. HRSA issued Policy Release 2014-1 to clarify that the use of the MEF should be limited to Medicaid FFS and associated compliance requirements.[5] CMS defers to HRSA for any questions related the MEF.

Developing Strategies with Contract Pharmacies

CMS is also aware that some states face challenges with avoiding duplicate discounts on 340B drugs dispensed by 340B contract pharmacies. Contract pharmacies may be unable to prospectively identify claims for 340B purchased drugs before billing states, because the prescriptions are not generally identified as 340B at the point of sale by the 340B covered entity. Collectively, states are responsible for retrospectively identifying claims, which is time consuming, often requires employing the services of contractors, and can be rather complex given the involvement of the number of contract pharmacies.

In 2010, HRSA issued recommended guidelines for covered entities that utilize contract pharmacies to dispense 340B purchased drugs to Medicaid FFS beneficiaries.[6] The guidance states that HRSA may not permit covered entities to dispense 340B drugs to Medicaid FFS beneficiaries through a contract pharmacy unless the covered entity has an approved contract pharmacy agreement to prevent duplicate discounts. The guidelines set forth that the 340B covered entity, the contract pharmacy and state Medicaid agency have established a three-party arrangement to prevent duplicate discounts. Such arrangements are to be reported to HRSA's Office of Pharmacy Affairs (OPA) by the covered entity.[7] A list of covered entities with approval from HRSA to dispense 340B drugs at their contract pharmacies to Medicaid FFS patients can be found at http://340bopais.hrsa.gov/reports.

Options for Medicaid Reimbursement for 340B Drugs Purchased by Covered Entities

To help assist with avoiding duplicate discounts, some state Medicaid programs have elected to use the state plan amendment (SPA) process to develop parameters around the ability of covered entities and/or contract pharmacies to dispense 340B drugs to Medicaid FFS beneficiaries. For example, a state can ask a covered entity to confirm in writing that it is using 340B purchased drugs for Medicaid patients. This can help states confirm the information that a covered entity is reporting to the Medicaid Exclusion File for FFS claims. A state could also use the SPA process to limit the ability of some or all of the covered entities and/or contract pharmacies in the state to use 340B purchased drugs for Medicaid beneficiaries. If the covered entity or contract pharmacy is not able to use 340B drugs for Medicaid beneficiaries, the pharmacy can remain a Medicaid provider and drugs can be purchased outside of the 340B program and dispensed to Medicaid patients. States should evaluate the individual needs of their program to determine if these approaches will provide the best quality of care to patients and assist in avoiding billing manufacturers for duplicate discounts.

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5 https://www.hrsa.gov/sites/default/files/opa/programrequirements/policyreleases/clarification-medicaid-exclusion.pdf

6 Notice Regarding 340B Drug Pricing Program—Contract Pharmacy Services; Final Notice. 75 Fed. Reg., 10278 (Mar. 5, 2010). https://www.gpo.gov/fdsys/pkg/FR-2010-03-05/pdf/2010-4755.pdf

7 Id

Using 340B Claims Identifier Options

Submission Clarification Code

The National Council for Prescription Drug Programs (NCPDP) has issued a claims modifier option as part of the NCPDP Telecommunication Standard version D.0.[8] This option allows a pharmacy to designate a 340B claim ineligible for a rebate prior to dispensing.

State Medicaid agencies choosing to use this NCPDP claims modifying mechanism can require pharmacies to submit a value of "20" in the Submission Clarification Code field of the NCPDP Telecommunication Standard and a value of "08" in the Basis of Cost Determination field to identify 340B claims. The Submission Clarification Code is issued to describe the claim and the Basis of Cost Determination describes the price. The Submission Clarification code has had very limited use, however, and NCPDP has indicated that in the future it plans to sunset the value in Telecommunication VF2 and greater versions. In the meantime, the Submission Clarification Code can be submitted on the point of service real time claim or added retrospectively to indicate that a drug within the pharmacy's physical inventory was purchased under the 340B Program.

"UD" Modifier or State-Specific Modifiers

The American National Standards Institute's (ANSI) Accredited Standards Committee (ASC) standard X12 837P "UD" modifier can be used to identify physician administered drugs purchased through the 340B Program. For physician administered drugs purchased through the 340B Program, states can instruct 340B covered entities to enter the ANSI "UD" modifier on the claim, and other appropriate claim forms (CMS 1500 837 or UB04 837), associated with the applicable Healthcare Common Procedure Coding System (HCPCS) code and national drug code (NDC) to properly identify 340B drugs.

Physician Administered Drugs Billing Modifiers for Dually Eligible Beneficiaries

Effective January 1, 2018, Medicare Part B has implemented two new 340B billing modifiers for use under the Hospital Outpatient Prospective Payment System (OPPS). These modifiers are required by the Medicare billing system to identify certain Part B drugs acquired under the 340B Program. Medicare has assigned modifier "JG" to relate to specific Medicare drug reimbursement, whereas Medicare is using the "TB" modifier for informational purposes.

More details on these modifiers can be found in online FAQs here: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Downloads/Billing-340B-Modifiers-under-Hospital-OPPS.pdf.

If the state receives a crossover drug claim containing either modifier for dual-eligible beneficiaries, the state should recognize that the drug was purchased under the 340B Program and not bill the manufacturer for a rebate. States that have dual-eligible beneficiaries enrolled in Medicaid managed care plans should instruct the Medicaid managed care plans to be aware of

8 https://www.ncpdp.org/Resources/Standards-Transition.aspx

these two new modifiers when the plan is complying with the contract term that implements 42 C.F.R. § 438.3(s)(3). Even without such a direction from the state, Medicaid managed care plans that must comply with a contract term implementing § 438.3(s)(3) should take these two new modifiers into account as part of its procedures to exclude utilization data for covered outpatient drugs that are subject to discounts under the 340B Program from the utilization reports that must be submitted to the state.

State Medicaid agencies may also wish to instruct their providers to include the "TB" modifier, along with the required NDC number, on all physician administered drug claims for drugs purchased under the 340B program. This will fulfill the states' requirement to provide a means for covered entities to identify 340B purchased drugs in order to prevent erroneously billing manufacturers for rebates and creating a duplicate discount.

Finally, states implementing this option should then exclude from Medicaid rebate billing all claims identified with either of these 340B claims identifiers, or any other state-specific 340B claim identifiers adopted for both (or either) FFS and managed care claims for covered outpatient drugs. By excluding claims that have been identified as drugs that were purchased using 340B discounts, states will avoid duplicate discounts on such claims.

Including 340B Duplicate Discount Provisions in Medicaid Managed Care Contracts

Additional steps must also be taken to safeguard against duplicate discounts on 340B claims when Medicaid managed care plans are responsible for payment of the covered outpatient drug. Consistent with the contract provision required by 42 CFR §438.3(s)(3), claims for 340B drugs that are the responsibility of the Medicaid managed care plan must be identified and excluded from the general managed care utilization data reported to the state for purposes of billing manufacturers for Medicaid rebates. This is the case when states do not require submission of managed care drug claims data from covered entities directly.

As specified in the MC Final Rule, states must include the requirements from 42 CFR §438.3(s)(3) in their managed care plan contracts; that provision requires the managed care plan to exclude utilization data for covered outpatient drugs that are subject to discounts under the 340B drug pricing program from the reports that managed care plans submit to the state when states do not require submission of managed care drug claims data from 340B covered entities directly. To help ensure that these requirements are met, states should also exclude these 340B claims in their drug utilization data reported to CMS quarterly for purposes of the Medicaid drug rebate program.

HRSA encourages 340B covered entities to work with the applicable state to develop strategies to prevent duplicate discounts on drugs covered by Medicaid managed care plans. HRSA has outlined best practices for covered entities in Policy Release 2014-1.[9]

9 https://www.hrsa.gov/sites/default/files/opa/programrequirements/policyreleases/clarification-medicaid-exclusion.pdf

Providing Claims Level Data to Manufacturers

Although there is not a requirement for states to do so, states may consider providing manufacturers with claims level data, along with drug rebate invoices, to facilitate compliance and to ensure there are no duplicate discounts. Generally, when states provide claims level data to manufacturers, we would expect there to be a reduction in number of disputes due to more accurate information being provided. As a reminder to states, the quarterly manufacturer Medicaid drug rebate invoices are summarized at the NDC11 level and sent to manufacturers without the underlying claims level data. However, manufactures likely need claims level data for true invoice validation purposes.

340B duplicate discounts can often best be identified from a review of claims level data by the manufacturers. Some states have chosen to provide their claims level data via a secured web portal managed by the state's invoicing vendor and/or an independent third-party data company. If claims level data is provided, this may reduce the state's administrative burden and expense of researching manufacturer dispute issues.

Using Specific Medicaid BIN/PCN on Medicaid Managed Care Plan Identification Cards

340B covered entities bill states for 340B prescriptions dispensed to Medicaid FFS beneficiaries through electronic claims, and use two codes to identify the beneficiary's health insurance and benefits - NCPDP Processing Bank Identification Number (BIN) and Processor Control Number (PCN). However, for 340B drugs dispensed to Medicaid managed care patients, many managed care plans have multiple lines of business that include Medicaid, commercial insurance, Medicare Advantage, and Marketplace coverage. In the absence of BIN and PCN identifiers unique to Medicaid managed care plans, it is difficult for the covered entities to determine whether the patient is a Medicaid managed care beneficiary or covered under another one of the managed care plan's other (non-Medicaid) lines of business, since a Group Number alone is not sufficient for Medicaid identification.

A best practice identified by states and stakeholders is for each Medicaid managed care plan and its pharmacy benefit managers (PBM(s)) to use a BIN/PCN combination that is unique to its Medicaid business (i.e., for claims for drugs dispensed to Medicaid beneficiaries), and thus distinguishable from the BIN/PCN combinations used for its other lines of business. In their contracts with Medicaid managed care plans, several states now require their plans to use specific BIN/PCN numbers to readily identify a Medicaid beneficiary. This provides an additional tool in the prevention of duplicate discounts. Specifically, covered entities that have opted to "carve-out" will know at the point of service whether to provide beneficiaries with medications purchased through the 340B Program.

The BIN/PCN unique identifier may also be valuable for the prevention of duplicate discounts where contract pharmacy arrangements exist. However, contract pharmacies must also be sure that the beneficiary presenting these Medicaid-specific cards at pharmacies that carve-in to 340B (i.e., contract pharmacies that have opted to use drugs purchased through the 340B Program for Medicaid beneficiaries) meets other applicable 340B patient eligibility tests, such as ascertaining that the Medicaid beneficiary received care at a 340B covered entity. HRSA's patient definition

guidelines can be found at https://www.hrsa.gov/sites/default/files/opa/programrequirements/federalregisternotices/patientandentityeligibility102496.pdf. Thus, the fact that a beneficiary has a Medicaid-specific BIN/PCN does not automatically mean they should receive a 340B drug.

Summary

CMS understands that preventing billing for duplicate discounts in the 340B Program can present challenges to state Medicaid programs, but there are potential best practices that can be employed requiring commitment from all stakeholders involved. In working to share and implement these best practices for avoiding duplicate discounts, CMS remains committed to providing access to all Medicaid beneficiaries and recognizes the important role that the 340B Program plays towards that goal.

If you have any questions regarding CMS guidance on 340B Best Practices, please email your questions to RxDRUGPolicy@cms.hhs.gov.