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Newsletter

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TO: Providers of Pharmaceutical Services – **For Action**
Hospitals, Federally Qualified Health Centers (FQHCs),
Independent Clinics, Health Maintenance Organizations – **For
Information Only**

SUBJECT: **State Coverage and Reimbursement for 340B Drugs**

EFFECTIVE: NJ FamilyCare (NJFC) pharmacy claims with service dates **on or
after April 1, 2017**

AIDS Drug Distribution Program (ADDP) pharmacy claims with
service dates **on or after July 1, 2017.**

PURPOSE: To notify providers of pharmaceutical services of the State's drug
coverage policy and procedures for billing **primary** 340B Drug Discount Program
(340B) claims to the NJFC and ADDP pharmacy benefit programs.

BACKGROUND: Federal law (42 USC 256b(a)(5)(A)(i)) prohibits duplicate discounts,
such that drug manufacturers are not required to reimburse states a Medicaid drug
rebate for drugs dispensed and paid at a 340B Drug Discount Program ceiling price.
Prior to adoption of the Covered Outpatient Drug Rule (CMS 2345-FC), New Jersey
avoided the possibility of duplicate discounts by excluding pharmacy claims paid by the
State based on information provided on the Health Resources and Services
Administration (HRSA) Medicaid Exclusion File. The HRSA File lists those providers
authorized by HRSA to dispense 340B drugs to NJFC-enrolled beneficiaries. With the
adoption of this Rule, the State will rely solely on claim level data to identify a 340B drug
claim and exclude only those claims from Medicaid drug rebate processing.

Sections 447.512(b) and 447.502 of the Social Security Act (SSA), also referred to as the
Covered Outpatient Drug Rule (CMS 2345-FC), established State Medicaid requirements
for reimbursement of covered outpatient drugs. CMS 2345-FC replaces Estimated
Acquisition Cost (EAC), the current basis for calculating ingredient drug costs, with Actual
Acquisition Cost (AAC) and replaces the pharmacy dispensing fee with a professional fee
(See the Medicaid Newsletter Volume 27, No. 03).

The 340B Drug Discount Ceiling Price will be a component of the 'lowest of' calculation to
be applied by the NJFC and ADDP programs, based on service date, to determine AAC
for ingredient drug costs. Section 340B is referred in the Public Health Service Act of

1992. Section 340B requires that drug manufacturers that have entered into the federal Medicaid Drug Rebate Agreement offer discounted prices, referred to as 340B ceiling prices, to certain covered entities, including, but not limited to disproportionate share (DSH) hospitals and federally qualified health centers (FQHCs). The 340B ceiling price is defined as a drug's Average Manufacturer's Price (AMP) minus a drug's federal Unit Rebate Amount (URA).

Only pharmacies operated by covered entities using 340B inventory are eligible to receive NJFC and ADDP payments for covered outpatient drugs when dispensed to a 340B-eligible beneficiary. A 340B-eligible beneficiary is defined as an individual who receives medical care, typically in an outpatient setting, from the covered entity. Contract pharmacies shall not be eligible to receive NJFC FFS payments for 340B prescriptions dispensed to 340B-eligible beneficiaries.

By definition, AAC means the actual prices paid by a pharmacy to acquire drug products marketed or sold by manufacturers. The maximum allowable ingredient drug cost, calculated based on an AAC, is defined as the **lowest of**:

- the National Average Drug Acquisition Cost (NADAC) Retail Price Survey, as compiled by Myers and Stauffer, LLC, on behalf of the Center for Medicaid and CHIP Services; or an alternative benchmark of Wholesale Acquisition Cost (WAC) less a volume discount of two (2) percent, in the absence of a NADAC price;
- the Federal Upper Limit (FUL) price for covered outpatient drugs ([see https://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Benefits/Prescription-Drugs/Federal-Upper-Limits.html](https://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Benefits/Prescription-Drugs/Federal-Upper-Limits.html));
- the State Upper Limit (SUL) price for covered outpatient drugs ([see https://www.njmms.com/downloadDocuments/Current_NJ_SUL_Rates_02-17-17.pdf](https://www.njmms.com/downloadDocuments/Current_NJ_SUL_Rates_02-17-17.pdf)) calculated as 100% of drug acquisition costs for covered outpatient drugs as determined by State-sponsored pharmacy surveys;
- the 340B Drug Discount Program ceiling price; or an alternative benchmark of WAC less a volume discount of twenty-five (25) percent in the absence of a 340B ceiling price, when applicable; or
- A pharmacy's usual and customary charge.

The Covered Outpatient Drug Rule also replaces the "dispensing fee" with a new "professional fee" as described in Section 447.502 of the SSA (See the Medicaid Newsletter Volume 27, No. XX).

ACTION: **Effective for claims with service dates on or after April 1, 2017**, the State shall provide NJFC drug coverage for 340B prescriptions dispensed to a 340B-eligible beneficiary by a pharmacy **operated by a covered entity**.

Effective for claims with service dates on or after July 1, 2017, the State shall provide ADDP drug coverage for 340B prescriptions dispensed to a 340B-eligible beneficiary by a pharmacy **operated by a covered entity**.

- Covered entities include DSH hospitals, FQHCs, and certain independent clinics.

- The definition of a 340B-eligible patient is set by each covered entity and typically refers to someone who receives medical care provided by a covered entity in an outpatient setting.
- The State anticipates having access to 340B ceiling prices. However, the Covered Outpatient Drug Rule requires the State to establish an alternative benchmark to ensure that 340B pricing remains a viable component of the 'lowest of' pricing calculation. The State, with CMS approval, has determined that the WAC less a volume discount of twenty-five (25) percent is a reasonable alternative pricing benchmark in the absence of a 340B ceiling price.

Regardless of service date, 340B ceiling prices do not apply to State-funded pharmacy benefit programs, including PAAD, SG and CF. Identified claims with service dates on or after July 1, 2017, shall be denied payment by Error Code 2296, "Claim not eligible for 340B pricing."

340B Billing Procedures

- Pharmacies operated by covered entities are required to report on FFS pharmacy claims the code value '08' in the National Council for Prescription Drug Programs (NCPDP) field **Basis of Cost Determination** (Field 423-DN) to indicate the dispensing of a 340B drug.
- Edit Code 2297 shall post to pharmacy claims reporting the **Basis of Cost Determination** code value of '08' identifying the dispensing of a 340B drug.

It is the responsibility of the 340B covered entity to correctly report claims filled with 340B stock for 340B-eligible patients to ensure rebates are not collected for these drugs. In the event the State receives a dispute from a manufacturer for a 340B prescription due to incorrect claim level identifiers, the 340B-covered entity will be held responsible and subject to the recovery of payment.

If there are any questions regarding this Newsletter, please contact Molina Medicaid Solutions Provider Services at 1-800-776-6334.

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