

**INFORMATIONAL LETTER NO. 2243-MC-FFS**

**DATE:** July 13, 2021

**TO:** Iowa Medicaid Hospital, Physician, Nurse Practitioner, Physician Assistant, Rural Health Clinic, Clinic, Community Mental Health Center, Federally Qualified Health Center, Family Planning Clinics, Nursing Facilities/Skilled Nursing Facilities, and Pharmacies

**APPLIES TO:** Managed Care (MC), Fee-for-Service (FFS)

**FROM:** Iowa Department of Human Services (DHS), Iowa Medicaid Enterprise (IME)

**RE:** Update – 340B Drug Pricing Program

**EFFECTIVE:** Immediately

**\*\*\*\*This Informational Letter (IL) replaces IL 1638-MC-FFS.\*\*\*\***

**A. Background**

- Oversight - The 340B Drug Pricing Program requires drug manufacturers to provide outpatient drugs to eligible health care organizations or covered entities (CEs) at significantly reduced prices. The Office of Pharmacy Affairs (OPA) is the office responsible for administering the 340B Program and is part of the Health Resources and Services Administration (HRSA). Other products available through the 340B pricing program include vaccines and diabetic supplies (lancets, meters, strips and syringes).
- Duplicate Discounts - Federal law prohibits duplicate discounts, which means that manufacturers are not required to provide a discounted 340B price and a Medicaid drug rebate for the same drug. It is imperative the CEs have procedures in place to accurately identify and submit each claim as outlined to prevent duplicate discounts.
- Medicaid Rebates – Medicaid is required by the Centers for Medicare and Medicaid Services (CMS) to submit claims paid for covered outpatient drugs to manufacturers for federal and supplemental rebates, when applicable. All claims that are not appropriately identified as being purchased via the 340B pricing program will be considered rebate-eligible and submitted for rebates.

## B. Definitions

- 340B Actual Acquisition Cost (340B AAC) – The net cost of a drug paid by a CE for drugs or products purchased through the 340B drug pricing program. A drug or product’s 340B AAC includes discounts, rebates, chargebacks and other adjustments to the price of the drug or product, but excludes dispensing fees.
- 340B CE – A facility eligible to purchase drugs or products through the 340B Program and that appears on the OPA Database within the HRSA.
- 340B Contract Pharmacy – A pharmacy under contract with a CE that lacks its own pharmacy whereby the contract pharmacy is authorized to dispense 340B discounted drugs on behalf of the CE.
  - Outpatient Drugs – Drugs provided through individual prescriptions to a patient and physician-/provider-administered drugs.
  - Pharmacy-Covered Outpatient Drug Claims – Drugs are dispensed to the patient, or to a long-term care facility.
  - Medical-Covered Outpatient Drug Claims – Drugs that are administered by the physician/provider in the provider’s office or in an outpatient setting.
- Fee-for-Service (FFS) – Providers bill Iowa Medicaid directly for prescriptions and physician-administered drugs they provide to FFS members.
- Medicaid Carve-In – A CE has determined they will use 340B purchased drugs for Medicaid members.
- Medicaid Carve-Out – A CE has determined they will purchase drugs for Medicaid members through mechanisms other than 340B.
- Physician/Provider Administered Drugs – Drugs billed as a physician service (e.g., billed with “J”, “S”, “Q”, or other applicable HCPCS Level II procedure codes).

## C. 340B CE Enrollment and Responsibility

1. Enrollment: In order to become eligible to participate in the 340B Program, the provider must submit a request to the OPA within HRSA. See the [OPA website](#)<sup>1</sup> and the [registration forms](#)<sup>2</sup>. **The CE must decide if they are carving Medicaid “OUT” or “IN”, and that decision applies to both FFS and MC claims.**
2. Update: To ensure that the information reported to the OPA is accurate, the 340B CE should:
  - a. Review the information listed for the CE on the [HRSA Medicaid Exclusion File](#)<sup>3</sup> located on the OPA website for accuracy and identify any inaccurate or missing information.
  - b. Report all changes and corrections to the OPA.

**D. Medicaid Requirements:** All 340B CEs that use 340B drugs and serve Medicaid (FFS and MC) members must do one of the following:

1. Medicaid CARVE-OUT all prescriptions, physician-administered drugs, and other products from the 340B program.

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<sup>1</sup> <http://www.hrsa.gov/opa/>

<sup>2</sup> <https://www.hrsa.gov/opa/program-requirements/index.html>

<sup>3</sup> <https://340bopais.hrsa.gov/SearchLanding>

- Use non-340B drugs, vaccines and diabetic supplies for all Medicaid (FFS or managed care) members you serve.
  - Bill only for drugs, vaccines and diabetic supplies purchased outside the 340B program billed in accordance with existing Medicaid (FFS or managed care) reimbursement methodologies, allowing rebates to be collected where appropriate.
  - Do not list the 340B entity's NPI on the HRSA Medicaid Exclusion File.
  - This allows rebates to be collected where appropriate.
2. Medicaid CARVE-IN all prescriptions, physician-administered drugs, and other products into the 340B program.
- Use 340B drugs, vaccines and diabetic supplies for all Medicaid (FFS or MC) members you serve.
  - Inform OPA at the time of 340B enrollment that you intend to purchase and dispense 340B drugs for Medicaid (FFS or MC) members.
  - Do not bill Medicaid (FFS or MC) for 340B acquired drugs and products if your NPI is not listed on the HRSA Medicaid Exclusion File.
  - Purchase all drugs and other products billed to Medicaid (FFS or MC) on the CE's NPI under 340B unless the product is not eligible for 340B pricing.
  - This ensures these claims are excluded from Medicaid rebate.

**BILLING:**

**a. Pharmacy**

1. Pricing: Submit pharmacy claims for 340B-acquired drugs to Medicaid (FFS or MC) at your 340B AAC.
2. 340B Claim Identifiers: Submit pharmacy claims for 340B-acquired drugs to Medicaid (FFS or MC) with values of "08" in Basis of Cost Determination field 423-DN OR in Compound Ingredient Basis of Cost Determination field 490-UE AND insert "20" in the Submission Clarification Code field 420-DK.
3. Non-340B Claim: If the product is not eligible for 340B pricing do not include the basis of cost determination or submission clarification code values and bill at the regular Medicaid (FFS or MC) rate.

**b. Medical – Physician-/Provider-Administered Drugs - The use of a modifier identified below is required on a clinician-administered claim line to indicate that a drug was acquired with the CE 340B discount.**

1. Pricing: Submit claim at your 340B AAC if Medicaid is primary, at Medicare policy if dual eligible.
2. 340B Claim Identified/Modifier: Submit claims for 340B-acquired drugs to Medicaid (FFS or MC) with the appropriate modifier on the Medicaid claim or Medicare Crossover claim submitted.

Electronic Billing – 837P or 837I Transactions

- UD Modifier – Drug or biological acquired with the 340B drug pricing program discount for members with Medicaid coverage only.

- 837P – “UD” modifier in Loop 2400 SV1, can send up to 4 modifiers in SV101-3, SV101-4, SV101-5, and SV101-6
  - 837I – “UD” modifier in Loop 2400 SV2, can send up to 4 modifiers in SV202-3, SV202-4, SV202-5, and SV202-6
  - **JG or TB Modifier** – Drug or biological acquired with the 340B drug pricing program discount for Medicare Part B drugs for Iowa Medicaid dual-eligible members. Effective January 1, 2018, CMS created the two new HCPCS Level II modifiers “JG and TB” to identify 340B for Medicare Part B drugs. CEs should utilize these two modifier codes to appropriately identify 340B Medicare Part B drugs to Medicare and must also report to Iowa Medicaid for dual-eligible members.
    - 837P – “JG or TB” modifier in Loop 2400 SV1, can send up to 4 modifiers in SV101-3, SV101-4, SV101-5, and SV101-6
    - 837I – “JG or TB” modifier in Loop 2400 SV2, can send up to 4 modifiers in SV202-3, SV202-4, SV202-5, and SV202-6
3. **Non-340B Claim:** If the product is not eligible for 340B pricing do not include a modifier and bill at the regular Medicaid (FFS or managed care) rate. See [IL 699](#)<sup>4</sup>.

**c. Vaccine and Diabetic Supply claims**

1. **Pricing:** Submit claims for 340B-acquired products to Medicaid (FFS or MC) at your 340B AAC.

3. **340B Contract Pharmacies:** Contract pharmacies may not submit claims to Medicaid FFS or MC for 340B-acquired drugs. A 340B contract pharmacy must carve out Medicaid FFS and MC from its 340B operation. Medicaid will submit all covered outpatient drug claims from contract pharmacies for federal and supplemental rebates, when applicable.

A 340B FAQ document and other helpful information is available [here](#)<sup>5</sup> to help answer questions.

If you have billing questions, please contact the IME Provider Services at 1-800-338-7909 or by email at [imeproviderservices@dhs.state.ia.us](mailto:imeproviderservices@dhs.state.ia.us)

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<sup>4</sup> [http://dhs.iowa.gov/sites/default/files/699\\_340BDrugProgram2RS2.pdf](http://dhs.iowa.gov/sites/default/files/699_340BDrugProgram2RS2.pdf)

<sup>5</sup> [http://www.iowamedicaidpdl.com/frequently\\_asked\\_questions](http://www.iowamedicaidpdl.com/frequently_asked_questions)