



Iowa Department of Human Services

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INFORMATIONAL LETTER NO.1404

DATE: July 17, 2014

TO: Iowa Medicaid Hospitals, Federally Qualified Health Centers, Rural Health Clinics, Screening Centers, Family Planning Clinics, Maternal Health Centers, Clinics and Pharmacies

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

RE: 340B Drug Pricing Program

EFFECTIVE: Immediately

A. Background

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 Health Resources and Services Administration (HRSA). 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. CEs must have procedures in place to prevent duplicate discounts. Other products available through the 340B pricing program include vaccines and diabetic supplies (lancets, meters, strips and syringes).

B. Definitions

- **340B Actual acquisition cost (340B AAC)** means 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** means a facility eligible to purchase drugs or products through the 340B Program and that appears on the OPA Database within the HRSA.
- **340B contract pharmacies** means 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.
- **Fee-for-Service (FFS)** means providers bill Iowa Medicaid directly for prescriptions and physician administered drugs they provide to FFS members.
- **Medicaid Carve-In** means a CE has determined they will use 340B purchased drugs for Medicaid members.
- **Medicaid Carve-Out** means a CE has determined they will purchase drugs for Medicaid members through mechanisms other than 340B.
- **Outpatient Drugs** means drugs provided through individual prescriptions to a patient and physician administered drugs.
- **Physician administered drugs** means drugs billed as a physician service (i.e., 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](#)¹ and the [registration forms](#)².
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](#)³ 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 Fee-for-Service (FFS) Providers: *New requirements or clarifications are bolded and highlighted.*

1. **340B Covered Entities:** All 340B CEs that use 340B drugs and serve Medicaid FFS members must do one of the following:

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

- Use non-340B drugs, vaccines and diabetic supplies for all Medicaid members you serve.
- Bill Medicaid only for drugs, vaccines and diabetic supplies purchased outside the 340B program billed in accordance with existing state Medicaid 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.

b) 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 members you serve.
- Inform OPA at the time of 340B enrollment that you intend to purchase and dispense 340B drugs for Medicaid members.
- Do not bill Medicaid 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 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:**
 1. Submit **pharmacy claims** for 340B-acquired drugs to Medicaid at your 340B AAC and with values of "08" in Basis of Cost Determination field 423-DN **OR in Compound Ingredient Basis of Cost Determination field 490-UE AND effective August 1, 2014, also insert "20" in the Submission Clarification Code field**

¹ <http://www.hrsa.gov/opa/>

² <http://www.hrsa.gov/opa/programrequirements/forms/index.html>

³ <http://opanet.hrsa.gov/opa/CEMedicaidExtract.aspx>

2. **420-DK.** 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 rate.
 3. Submit **physician administered drug claims** for 340B-acquired drugs to Medicaid at your 340B AAC and with a “UD” modifier included on the UB04 or CMS 1500 claim forms. If the product is not eligible for 340B pricing do not include the “UD” modifier and bill at the regular rate. See [Informational Letter No. 699](#)⁴.
 4. Submit **vaccine and diabetic supply claims** for 340B-acquired products to Medicaid at your 340B AAC on the UB04 or CMS 1500 claim forms.
 5. For **Medicare Crossover Claims** (claims filed to Medicare that cross-over to Medicaid) **the “UD” modifier is also required for 340B-acquired physician administered drug claims.**
2. **340B 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.
3. **340B Drugs and Manufacturer Price Adjustment**
- Manufacturers periodically adjust Average Manufacturer Price (AMP) and Best Price (BP) values previously submitted to the Centers for Medicare and Medicaid Services (CMS) for certain quarters for specific products.
 - In connection with that recalculation, the manufacturer also recalculates the 340B ceiling prices for the affected products for the associated quarters.
 - Based on these recalculations the manufacturer communicates with and issues refunds to 340B CEs.
 - The IME will release clarifying information regarding 340B drugs and manufacturer price adjustment at a later date.

E. Medicaid Managed Care Providers

1. **340B Covered Entities:** All 340B CEs that use 340B drugs and serve Medicaid managed care members must do one of the following:

- a) **Medicaid CARVE OUT all physician-administered drugs from the 340B program**
- Use non-340B physician-administered drugs for all Medicaid managed care members you serve.
 - Do not list the 340B entity’s NPI on the HRSA Medicaid Exclusion File.
 - This allows rebates to be collected where appropriate based on the encounter data provided to Medicaid.

⁴ http://dhs.iowa.gov/sites/default/files/699_340BDrugProgram2RS2.pdf

b) Medicaid CARVE IN all physician-administered drugs into the 340B program

- Use 340B physician-administered drugs for all Medicaid managed care members you serve.
- Inform OPA at the time of 340B enrollment that you intend to purchase and dispense 340B drugs for Medicaid members.
- Do not use 340B acquired physician-administered drugs for Medicaid managed care members if your NPI is not listed on the HRSA Medicaid Exclusion File.
- Purchase all physician-administered drugs for Medicaid managed care members 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:**
 1. Submit **physician administered drug claims** for 340B-acquired drugs with a "UD" modifier included on the UB04 or CMS 1500 claim forms.

Attached to this Informational Letter is a FAQ document to help answer questions providers may have. If you have any additional questions please contact the IME Provider Services Unit at 1-800-338-7909, or locally in Des Moines at 515-256-4609 or by email at imeproviderservices@dhs.state.ia.us.

FAQs Regarding 340B Drug Pricing Program

Policy

- a. **How does a facility enroll in the 340B program?** Entities that are eligible for enrollment into the 340B program can find detailed information about enrollment on the [Health Resources and Services Administration's \(HRSA\) Office of Pharmacy Affairs \(OPA\) Webpage](#)⁵.
- b. **What is the general policy for obtaining rebates on 340B acquired drugs?** Iowa Medicaid does not submit 340B provider claims for rebate. The Health Resources and Services Administration (HRSA) Medicaid Exclusion File is used as the source of identifying 340B providers.
- c. **Do these requirements apply to all drugs/products?** This requirement applies to all 340B acquired drugs and products for outpatient use.
- d. **Do covered entities have to carve-in or carve-out 340B acquired drugs and products for Iowa Medicaid members?** Covered entities (CEs) may choose to carve-in or carve-out 340B acquired drugs and products for Iowa Medicaid members. If drugs and products are carved out, all claims for Iowa Medicaid members must be submitted for drugs and products purchased outside of the 340B program. If the covered entity chooses to carve-in, they must notify HRSA of the intent to purchase and dispense 340B drugs to Medicaid members.
- e. **Can an Iowa Medicaid provider enrolled in the 340B federal drug pricing program charge the Iowa Medicaid program something other than their 340B actual acquisition cost (AAC)?** If the covered entity (CE) carves in all prescriptions, physician-administered drugs, and other products into the 340B program for Medicaid, the provider must charge Medicaid no more than their 340B AAC for the drugs or products. This includes vaccines and diabetic supplies (lancets, meters, strips and syringes).
- f. **Does the State Medicaid Agency seek a Medicaid Rebate on claims for members:**
 1. **That are “Dual Eligible” (Medicaid/Medicare)?** Yes, if Iowa Medicaid pays a portion of the claim, the claim will be submitted for rebates.
 2. **That received physician administered drugs?** Yes.
 3. **That are billed from Medicaid Managed Care?** Yes.

Physician Administered Drugs and Other 340B Products

- a. **Is there a claim modifier that must be used for billing 340B acquired physician administered drugs?** If the covered entity (CE) carves in all physician-administered drugs into the 340B program for Medicaid, submit physician administered drug claims with a “UD” modifier included on the UB04 or CMS 1500 claim forms.

⁵ <http://www.hrsa.gov/opa/eligibilityandregistration/index.html>

- b. Is there a claim modifier that must be used for billing other 340B acquired products such as vaccines or diabetic supplies?** If the covered entity (CE) carves in all 340B acquired products for Medicaid, no modifier is required when submitting the 340B claim for these items.
- c. Are intrauterine devices (IUDs) and other physician inserted products included in the 340B actual acquisition cost (AAC) submission requirement?** Any drug or product acquired by the covered entity (CE) through the 340B pricing program must be submitted to Medicaid at the 340B CE's acquisition price.
- d. How does our facility bill for a drug that is not eligible through the 340B drug pricing program if our facility has chosen to "carve in"?** If a drug is not eligible for 340B pricing do not include the "UD" modifier and bill at the regular Medicaid rate.
- e. How does our facility bill for a product (vaccine or diabetic supply) that is not eligible through the 340B drug pricing program if our facility has chosen to "carve in"?** If a product (vaccine or diabetic supply) is not eligible for 340B pricing, bill at the regular Medicaid rate.
- f. Does the 340B billing requirement apply to Medicaid Managed Care claims?** The "UD" modifier is required for 340B acquired physician administered drugs, but reporting of the 340B AAC is dictated by the Managed Care Organization.
- g. Does the 340B billing requirement apply to Medicare Crossover claims?** The "UD" modifier is required for 340B acquired physician administered drugs, but reporting of the 340B AAC for the 340B drug is not.

Pharmacy

- a. Is there a claim modifier that must be used for pharmacy claims?** Submit pharmacy claims for 340B-acquired drugs to Medicaid with a value of 20 in the Submission Clarification Code field 420-DK.
- b. How does our facility bill for a drug that is not eligible through the 340B drug pricing program if our facility has chosen to "carve in"?** If the product is not eligible for 340B pricing do not include the value of "08" in the Basis of Cost Determination field 423-DN or a value of "20" in the Submission Clarification Code field 420-DK and bill at the regular Medicaid rate.
- c. Is there a different dispensing fee for a 340B pharmacy?** The dispensing fee is the same for all Iowa Medicaid pharmacies.
- d. What is the requirement for 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.