



Iowa Department of Human Services

Terry E. Branstad
Governor

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Director

INFORMATIONAL LETTER NO. 1344

DATE: January 28, 2014

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

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

RE: 340B Drugs and Manufacturer Price Adjustment

EFFECTIVE: Immediately

Background: The 340B Drug Pricing Program resulted from enactment of the Veterans Health Care Act of 1992, which is Section 340B of the Public Health Service Act. 340B providers are able to acquire drugs through that program at significantly discounted rates. The significant discount applied to the cost of these drugs make them ineligible for the Medicaid drug rebate. State Medicaid programs are obligated to ensure that rebates are not claimed on these drugs.

Billing of 340B Claims: When billing Medicaid, drugs acquired through the 340B Drug Pricing Program and used for Medicaid members must be submitted to Medicaid at their 340B actual acquisition cost (340B AAC).

- 1. For Pharmacy Claims:** 340B AAC is submitted in the Ingredient Cost field (4Ø9-D9) with the Basis of Cost Determination (423-DN) indicator of "Ø8".
- 2. For Medical Claims:** 340B AAC is reported in the charge box of any claim with the "UD" modifier for any physician-administered drugs billed with a "J" code.

Adjustments to 340B Claims: 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 Covered Entities (CEs) where the data demonstrates a difference between the original and recalculated 340B ceiling prices paid during impacted quarters by such CEs for the impacted products. Providers are required to adjust their 340B claims submitted to Medicaid to reflect any price reductions received through this process. Claims are considered overpaid if the cost of the 340B drug is reduced after Medicaid makes payment for the 340B drug. Newly enacted Iowa Administrative Code (IAC) 441-79.2(10) requires that providers return an overpayment within 60 days of identification of the overpayment. (Iowa Code section 249A.39 (Supp. 2013). Providers who fail to return an overpayment in accordance with IAC 441-79.2(10) may be subject to damages and penalties under Iowa Code Chapter 685 (Iowa False Claims Act) and civil monetary penalties under Iowa Code section 249A.47, and subject to liability under other state and federal regulations and statutes.

If you have any questions please contact the IME Provider Services Unit at 1-800-338-7909, locally in Des Moines at 515-725-1004 or by email at imeproviderservices@dhs.state.ia.us.