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APR 1 2004

Dear Manufacturer:

This letter provides information about two provisions in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) which affect the Drug Pricing Program established by section 340B of the Public Health Service Act. One provision exempts inpatient drug prices from best price reporting for purchases made by disproportionate share hospitals (DSH) participating in the 340B program. This provision may encourage more eligible DSHs to participate in 340B. The other raises the disproportionate share adjustment percentage for small rural and urban hospitals. This provision may make about 1,000 additional hospitals eligible to participate in the 340B program.

Section 1002 of the MMA, "Clarification of Inclusion of Inpatient Drug Prices Charged to Certain Public Hospitals in the Best Price Exemptions for the Medicaid Drug Rebate Program," amends the section of the Medicaid Rebate law (section 1927(c)(1)(C)(i)(I) of the Social Security Act) that specifies which prices paid for drugs are to be excluded from the quarterly best price reported by drug manufacturers to the Centers for Medicare & Medicaid Services (CMS). The amendment adds inpatient prices charged to DSHs participating in the 340B drug pricing program to the list of exemptions. This provision was effective on December 8, 2003. This provision should make it possible for your company to sell inpatient drugs to these DSHs at lower prices, now that these prices no longer have the potential to lower prices paid by other customers or increase your rebate payments to Medicaid state agencies.

Section 402 of the Act, "Enhanced Disproportionate Share Hospital (DSH) Treatment for Rural Hospitals and Urban Hospitals with Fewer than 100 Beds," changes the DSH adjustment for a hospital that is not a large urban hospital to the same adjustment formula used for large urban hospitals, subject to an overall cap of 12%. Rural referral centers are not subject to the cap. If this new adjustment process results in an adjustment percentage that is greater than 11.75, the DSH may be eligible to register as a covered entity authorized to purchase outpatient drugs at 340B prices. The actual adjustment percentage for each hospital will be determined by the CMS.

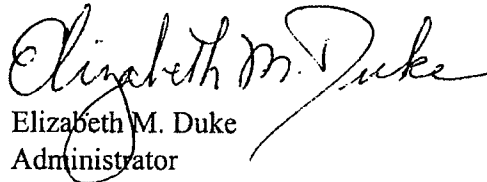
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To become eligible for the 340B program, the DSH must also meet the two other statutory criteria, as specified by section 340B(a)(4)(L) of the Public Health Service Act:

- Be owned or operated by a unit of State or local government, be a public or private non-profit corporation which is formally granted governmental powers by a unit of State or local government, or be a private non-profit hospital which has a contract with a State or local government to provide health care services to low-income individuals who are not entitled to benefits under title XVIII of the Social Security Act or eligible for assistance under the Medicaid State plan and
- Not obtain covered outpatient drugs through a group purchasing organization or other group purchasing arrangement.

If you need any additional information about the impact of these provisions on the 340B program, please contact HRSA's Pharmacy Affairs Branch Pharmacy Support Services Center at 1-800-628-6297.

Sincerely,



Elizabeth M. Duke  
Administrator