



JAN 30 2007

Rockville MD 20857

Dear Pharmaceutical Manufacturer:

The Office of Pharmacy Affairs (OPA), within the Healthcare Systems Bureau of the Health Resources and Services Administration, is charged with administering the drug pricing program established by Section 340B of the Public Health Service Act. Section 340B requires that participating pharmaceutical manufacturers charge covered entities a price for covered outpatient drugs that does not exceed the average manufacturer price decreased by the Medicaid rebate percentage (the "340B ceiling price") as specified in the statute.

OPA is writing to clarify for manufacturers the definition of Average Manufacturers Price that is used for 340B ceiling price calculations (340B AMP). Although the Deficit Reduction Act amended the statutory definition of Average Manufacturers Price for purposes of Medicaid by removing the deduction for customary prompt payment discounts, Section 340B(c) of the Public Health Service Act states, "Any reference in this section to a provision of the Social Security Act shall be deemed to be a reference to the provision as in effect on the date of the enactment of this section." Accordingly, manufacturers that have signed pharmaceutical pricing agreements (PPAs) must continue to calculate 340B ceiling prices so that the calculated price continues to reflect a reduction for any prompt payment discounts.

We welcome comments from all parties about how to best implement the 340B Program requirements in the wake of changes in related areas impacted by the DRA. Our goal would be to minimize the burden on pharmaceutical manufacturers in submitting the required data.

As part of OPA's efforts to improve the administration of the 340B Program as outlined previously in our letter to pharmaceutical manufacturers dated December 30, 2005, we also continue to invite all pharmaceutical manufactures that have signed 340B PPAs to voluntarily submit quarterly 340B price files on covered outpatient drugs to OPA.

Please feel free to contact LT Devin Williams of OPA at 301-594-4356 (email: [DWilliams@HRSA.GOV](mailto:DWilliams@HRSA.GOV)) with any questions you may have. We appreciate your continued participation in and commitment to the 340B Program. Your cooperation will make a significant contribution to ensuring the fairness and integrity of the 340B Drug Pricing Program.

Sincerely,

Jimmy R. Mitchell, R.Ph, MPH, MS  
Director  
Office of Pharmacy Affairs