



The Monitor

The Inside Source on the Public Health Service 340B Drug Discount Program

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BREAKING NEWS ALERT

OPA Issues “Dear Manufacturer” Letter on Key 340B Pricing Component

The Office of Pharmacy Affairs (OPA), the government agency that oversees the 340B drug discount program, has issued a “Dear Manufacturer” letter concerning the calculation of average manufacturer price (AMP), a key pricing component in calculating 340B ceiling prices.

The letter, which OPA says aims to clarify the definition of AMP used in the 340B program, states that “manufacturers that have signed pharmaceutical pricing agreements must continue to calculate 340B ceiling prices so that the calculated price continues to reflect a reduction for any prompt payment discounts.”

The Deficit Reduction Act (DRA) of 2005 removed consideration of prompt pay discounts from AMP calculations. The Centers for Medicare and Medicaid Services recently proposed alterations to AMP calculation, including the removal of prompt pay discounts, as well as other changes not explicitly specified under the DRA. (See January’s *Monitor*.)

OPA, however, contends that statutory changes to the definition of AMP made after the enactment of the 340B statute in 1992 do not apply to AMPs used in calculating 340B prices, a position that the pharmaceutical industry believes will create unreasonable burdens for manufacturers. (See December’s *Monitor*.)

The letter can be found at <http://www.hrsa.gov/opa/pharm-mfg-ltr013007.htm>. More details, as well as reaction from providers and industry, will be available in February’s *Monitor*. In addition, there will be an in-depth look at this and other issues at the Third Annual 340B Coalition Winter Conference, which will be held from February 26-28th in Salt Lake City, Utah. For more information about the conference, go to http://www.340bconferences.org/conferences/2007_winter/.