

for the 12-month period ending June of the prior year.

As an example of how this approach might apply to a specific drug assuming an average AWP discount of 15 percent, we will again examine docetaxol (J9170). The April 1, 2003 AWP published in the commercial compendia for docetaxol is \$377. Applying an average AWP discount of 15 percent, the Medicare 2004 payment limit for J9170 would be \$320. Assuming a 4.0 percent increase in the consumer price index (CPI) for medical care for the 12-month period ending June 2004, the 2005 payment limit for J9170 would be \$333, regardless of the list AWP at that time.

*b. New Drugs and Drugs With Patent Expirations*

The reimbursement rate for new drugs and drugs coming off of patent would be determined for the first year based on our review of information provided by the manufacturer about the expected widely available market price for that year. As a condition of obtaining a HCPCS code for billing purposes (in the case of new drugs) or continuing to recognize a HCPCS code for billing purposes (in the case of drugs coming off patent), manufacturers would be required to provide information on the anticipated widely available market price that a prudent physician or prudent supplier would pay for the drug and a rationale for the new price. We expect that drug manufacturers in the normal course of conducting their business have determined the prices that physicians and suppliers would pay for the drug when sold through a distributor or via direct distribution.

If we suspect that a manufacturer has knowingly supplied misleading pricing information to generate or maintain a "spread" between Medicare payment and the widely available market price, we will refer the matter to the OIG. As stated by the OIG in their Office of Inspector General's Compliance Program Guidance for Pharmaceutical Manufacturers (68 FR 23737) that was published on May 5, 2003:

"If a pharmaceutical manufacturer purposefully manipulates the AWP to increase its customers' profits by increasing the amount the federal health care programs reimburse its customers, the anti-kickback statute is implicated. Unlike bona fide discounts, which transfer remuneration from a seller to a buyer, manipulation of the AWP transfers remuneration to a seller's immediate customer from a subsequent purchaser (the federal or state government). Under the anti-kickback statute, offering remuneration to a purchaser or referral source is improper if one purpose is to induce the purchase or referral of program business. In other words, it is illegal for a manufacturer knowingly to establish or

inappropriately maintain a particular AWP if one purpose is to manipulate the 'spread' to induce customers to purchase its product."

During the first year the HCPCS code is used for billing, the manufacturer would provide updated information to us on the actual prices that physicians and suppliers are paying to purchase the drug. Again, we expect manufacturers would collect this information in the normal course of conducting their business.

We would review this data and other available data sources on the widely available market price of the drug to determine if an adjustment to the Medicare payment limit would be required for the second year. In the absence of a second year adjustment, the first year payment would be updated by the increase in the medical component of the CPI for the 12-month period ending six months prior to the year. For the third year and all subsequent years, the Medicare payment limit would be updated on an annual basis by the increase in the CPI for medical care for the 12-month period ending June of the prior year.

*Option 3—Market Monitoring*

Another option we are proposing is to utilize existing sources of market-based prices in developing Medicare payment limits and to develop additional sources of this information for market monitoring. Under this option, we would define AWP to be the widely available market price. Initially, we would use the market analyses available to us from GAO and OIG studies to transition widely available market prices into the Medicare payments. As discussed below, over time we may expand our data sources for these market prices. Although the GAO and OIG performed market analyses on drugs covering the majority of Medicare expenditures, they did not study all of the approximately 450 Medicare drugs. As described earlier in section I.B, Medicare drug spending is concentrated in relatively few drugs; 33 drugs account for 86 percent of the spending. Initially, for those drugs where we do not have GAO and OIG information on which to base a market price, we would proceed as in option 2 and base the payment limit on an average AWP discount off of the list AWP reported to the commercial compendia as of April 1, 2003.

*a. Definition of Average Wholesale Price*

In implementing sections 1842(o) of the Act and 429 of BIPA, we propose to define the AWP of a drug to be the widely available market price. The widely available market price would be

the price that a prudent physician or prudent supplier would pay when purchasing the drug from common sources. Common sources that a prudent physician or supplier might utilize when purchasing a drug include, but are not limited to, wholesalers, manufacturers, repackagers, physician supply houses, pharmacies, specialty pharmacies, and group purchasing organizations. The widely available market price would not be a list price that is commonly discounted, but would be the purchase price net of discounts, rebates, and price concessions routinely available to prudent purchasers.

The widely available market price would reflect prices in programs where a manufacturer, a manufacturer's subsidiary or related company, or a repackager sells drugs to physicians and suppliers directly or through buying groups or other mechanisms. For example, if a drug manufacturer establishes a buying group easily accessed by prudent physicians, the lower price offered to the buying group should be reflected as the widely available market price.

It is not our intent to set the Medicare payment limit below the widely available market price. Under the current system, the Medicare allowed charge is the lower of the actual charge and 95 percent of the AWP. Using the authority granted to the Secretary under section 429(b) of BIPA, the Medicare allowed charge in a fully phased-in revised payment methodology would be the lower of the actual charge or the widely available market price. We would not pay at 95 percent of the widely available market price since we wish to consider further the issue of beneficiary access at 95 percent of the widely available market price. As described in section II.D, we do not expect any beneficiary access issues with payment at the widely available market price.

*b. Use of existing sources of market based prices*

As described earlier in section I.F, both the GAO and OIG have performed market analyses of the widely available market prices for the top Medicare drugs in terms of expenditures. While the market analyses differed in their methodologies, for example the GAO used averages of drug prices from their data sources and the OIG used medians, in general the results were consistent for these drugs. To begin to incorporate this information into the Medicare payment limits for the drugs that have been studied, we would take the average discount between the GAO and OIG data for the drug and apply it to the list AWP reported in the published