

compendia as of April 1, 2003.

Although as noted the results of the GAO and OIG market analyses are generally consistent, we seek comment on our proposed approach of averaging these two data sources.

For example, one drug studied by both the GAO and OIG is rituximab (J9310). The April 1, 2003 list AWP published in the commercial compendia for rituximab is \$501.13 for 100 mg. The GAO study indicates the average market price for rituximab is 81 percent of the list AWP. The OIG study indicates the average market price for rituximab is 80 percent of AWP. The average of these two data sources rounded to nearest percent is 81 percent of the list AWP. Under this option, the Medicare payment limit for J9310 would be \$405.92 (that is, 81 percent of \$501.13) effective January 1, 2004.

Clotting factor was the subject of a separate GAO report entitled "Payment for Blood Clotting Factor Exceeds Providers' Acquisition Costs" (GAO-03-184). This report found that the market price for clotting factor was 59 percent of list AWP for hemophilia treatment centers and 69 percent of list AWP for homecare companies. We are proposing to transition these market prices into the Medicare payment limit for clotting factor at the average of these two figures, 64 percent, with an initial transition amount of 80 percent in 2004. (see section 3.f. for further discussion on the transition to market prices). We are requesting comments on the appropriate payment limit rate. The limit would apply for all clotting factor HCPCS codes, including both the human and recombinant forms.

#### *c. Drugs Without Market-Based Price Information*

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 the average AWP discount off of the list AWP reported to the commercial compendia as of April 1, 2003.

As an example of how this approach might apply to a specific drug assuming an average AWP discount of 15 percent, we will examine ifosfamide (J9208). The OIG and GAO did not study ifosfamide. The April 1, 2003 list AWP published in the commercial compendia for ifosfamide is \$158. The Medicare payment limit for J9208 would be \$135 (that is, 85 percent of \$158) effective January 1, 2004.

#### *d. Exceptions Process for First Year Reductions*

A manufacturer could seek an exception from the application of these reductions on January 1, 2004 to one or

more of its drugs if it would furnish us before October 1, 2003 with verifiable data on the widely available market price, as described earlier in section II.A.3.a, of the drug as of April 1, 2003 and certify the accuracy of this data. We will review the data and determine if it should be incorporated into the Medicare payment limit. Note that all data submitted as part of comments on this proposed rule would be available to the public. Also note that we would base any changes to our proposed payment policy only on data that we could make available to the public.

#### *e. Future Years*

As discussed in section 3.f below, we expect to develop additional sources of market-based prices in future years for the purpose of market monitoring. We also recognize that the OIG may perform updated market analyses on drugs previously studied or additional drugs. If the OIG performs a new market analysis, we expect to incorporate this information into the Medicare payment limits. As we develop additional sources of widely available market prices and sufficient new valid information becomes available from these sources, we expect to incorporate this information into the Medicare payment limits based on the methodology described above. In the absence of additional valid data sources indicating a change in the widely available market price, the Medicare payment limits 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.

#### *f. Transition for Existing Drugs*

For existing drugs where the widely available market price based on the OIG and GAO studies is less than 80 percent of list AWP, we would transition to the market-based payment in 15 percentage point increments. This is similar to the approach taken by the Congress in specifying the incremental payment changes under the inherent reasonableness authority (section 1842(b)(8) of the Act). For example, one drug studied by both the GAO and OIG is ipratropium bromide (J7644). The April 1, 2003 AWP published in the commercial compendia for ipratropium bromide is \$3.52. The GAO study indicates the average market price for ipratropium bromide is 33 percent of list AWP. The OIG study indicates the average market price for ipratropium bromide is 34 percent of list AWP. The average of these two data sources rounded to the nearest percent is 34 percent of AWP. Because this is lower than 80 percent of list AWP, the Medicare payment limit for ipratropium bromide effective January 1, 2004 would

be 80 percent of the list AWP or \$2.82. The Medicare payment limit for ipratropium bromide effective January 1, 2005 would be 65 percent of the list AWP published in the commercial compendia as of April 1, 2003 updated by the medical CPI. The Medicare payment limits for CY 2006 and CY 2007 would be 50 percent and 35 percent, respectively, of the April 1, 2003 list AWP updated by the medical CPI. In 2008, the transition to the widely available market price would be complete and the payment limit would be 34 percent of the April 1, 2003 list AWP updated by the medical CPI.

To the extent that the OIG performs a new market analysis or additional data sources are developed as described in section 3.h, the target widely available market price might change.

#### *g. New Drugs and Drugs with Patent Expirations*

The payment limit for new drugs and drugs coming off of patent would be determined as described under option 2. The only difference would be that under the market monitoring approach the out year payment limit might change to the extent that the OIG performs a market analysis or additional data sources are developed as described in the next section.

#### *h. Additional Sources of Market-Based Prices*

We are considering additional sources of market-based price information. These sources could include drug distributors (for example, wholesalers, physician supply houses, specialty pharmacies, retail pharmacies, manufacturers, repackagers) physicians, suppliers, and group purchasing organizations (GPOs). To the extent that payments by private insurers and health plans reflect widely available market prices, we are considering inclusion of these sources.

The general approach we will use is to take the median price among valid available sources of information on widely available market prices, after making any adjustments required to make the information comparable. We are considering whether to restrict the median calculation to those information sources that reflect significant market share. We are proposing to rely on a single information source if we determine that the source is representative of the widely available market price for a drug.

We are considering the acquisition of this market-based price information through market research firms, contractors, consultants, the OIG, and/or by directly obtaining such data.

If we obtain additional sources of market-based prices and if we determine