

these sources are valid for the purposes of determining payment limits based on widely available prices, we will provide an opportunity for public comment on the sources.

1. Data from Distributors and Manufacturers

We would seek to acquire data from drug distributors and manufacturers. Although there may be many distributors for a given drug, our understanding is that most physicians and suppliers tend to use the same distributors over a given time period and that the majority of these purchases, at least for injectable drugs, are concentrated in a small number of distributors. We are considering whether to focus our efforts initially on these distributors and we are seeking comment on this focused approach.

Our market analyses would also include pricing information from manufacturers' direct distribution programs since, as discussed earlier, we understand that many of these programs are easily accessible to physicians and suppliers and that the prices offered in these programs are often lower than the prices available through other distribution channels.

2. Data From Physicians and Suppliers

We would also seek to obtain acquisition cost information from physician and suppliers. Although individual invoice pricing may not necessarily be reflective of the widely available market price, for example due to the presence of volume related rebates and price concessions, this information could be informative in developing the widely available market price.

While issues have been raised in the past concerning the use of invoice prices due to the potential presence of volume discounting, we note that the GAO study found that physicians who billed for low amounts of chemotherapy drugs were still able to obtain significant price discounts. We seek comment on this issue.

3. Data from Private Insurers and Health Plans

We are considering obtaining data from private insurers and health plans, including Medicare carriers' private businesses. As discussed earlier, it is our understanding that while many private insurers pay widely available market prices for oral drugs and inhalation drugs, they have not historically paid widely available market prices for injectable drugs. Given this, we are considering initially seeking private business prices for oral and

inhalation drugs. For example, we are considering whether to request our four DMEPOS contractors to supply us with oral and inhalation drug pricing and related information from their private side business.

For injectable drugs, as private insurers develop alternative payment approaches that reflect widely available market prices, we could seek this information from them. For example, similar to the approach suggested for oral and inhalation drugs, we are considering asking our carriers to furnish us with their private business payments for these drugs.

4. Approaches to Acquiring Market-Based Pricing Information

We are considering the acquisition of this market-based price information through market research firms, consultants, contractors, the OIG, and/or directly obtaining such data. It is our understanding that many manufacturers use market research firms to gather information on their products. For example, they conduct surveys of physician practices and compile pricing information. We are considering contracting with one of these firms to perform a market analysis of physician practices. We also understand that a few private health plans have begun to use consultants, at least for injectable drugs, to assist them in developing market-based payment structures. We are considering contracting with these consultants. We are considering an attempt to obtain pricing information directly from distributors using full or part-time CMS employed or contracted physicians. We are considering the selection of one or more contractors to acquire this information for us and maintain updated pricing information. The OIG may also update market analyses of drugs they have previously studied and examine additional drugs.

Option 4—Competitive Acquisition Program and Average Sales Prices

A fourth option we are considering is the establishment of a competitive acquisition program for drugs covered under section 1842(o) of the Act coupled with the establishment of a process for determining Average Sales Price (ASP). Under this option, we would establish competitive acquisition areas and entities would bid to supply drugs to physicians in one or more of these areas. A physician could choose annually to acquire drugs from one of these entities and the entity would be responsible for billing Medicare. Alternatively, a physician could choose to purchase drugs and bill Medicare. If a physician elected to purchase drugs,

we would pay the physician the ASP for the drug. Manufacturers would be required to furnish us with the ASP for each of their drugs quarterly. This option is consistent with the GAO's recommendation that we evaluate expanding competitive bidding approaches to obtain lower drug prices (GAO-01 1118, p.5) and is consistent with our understanding of Congressional intent with respect to section 429 of BIPA.

Below we describe our proposed competitive acquisition program and ASP-based payment systems. We seek comment on any additional elements that need to be considered in the establishment of these payment systems. We also note that for some drugs, such as those currently provided directly from the manufacturer to the physician, we may be potentially introducing an additional distribution level in the form of the bidding entity. Therefore, we have explicitly identified safeguards under the competitive acquisition program that are more implicit under our alternative payment reform proposals. While we believe that section 429 of BIPA contemplates (and section 1842(o) of the Act could be defined to permit) the use of such a competitive acquisition model, coupled with the implementation of an ASP setting function described below, we specifically solicit comments on the extent of the authority to implement the option set forth below either in its entirety or in a modified fashion.

A. Competitive Acquisition

1. Categories of Drugs

Under this proposal, we would bid two categories of drugs in each competitive acquisition area: oncology and non-oncology. The oncology category would consist of covered drugs typically billed by oncologists or otherwise used to treat cancer. The non-oncology category would consist of all other covered drugs with the exception of DME drugs, clotting factors, drugs furnished to individuals in connection with the treatment of end stage renal disease, and vaccines. Payment for excepted drugs would be based on the ASP. We may propose subcategories of non-oncology drugs in the future. We seek comment on any additional categories of drugs that may be inappropriate for competitive bidding due to low utilization, a unique method of delivery, or similar reasons.

2. Bidding Entity Qualifications

a. Capacity

Bidding entities would be required to demonstrate sufficient capacity to