

supply the drugs in the drug category in accordance with all applicable state requirements and pharmacy laws. The entity would need to have sufficient arrangements to acquire and to deliver drugs within the category at the bid price for all physicians that may elect such entity in a competitive acquisition area.

*b. Shipment*

Bidding entities would be required to have arrangements in effect for the shipment of drugs at least 5 days each week and for the timely delivery (including emergency situations) of drugs in the competitive acquisition area. The shipments would be made to the physician and not directly to the beneficiary, except under circumstances where a beneficiary currently receives the drug in the home or other nonphysician office setting. The contractor would not deliver drugs to a physician except upon receipt of a prescription.

*c. Integrity of the distribution system.*

Bidding entities would need to demonstrate that the drugs provided in the competitive acquisition program would be acquired directly from the manufacturer or from a distributor that has acquired the drugs directly from the manufacturer.

*d. Inquiries and dispute resolution.*

Bidding entities would be required to establish procedures for the prompt response and resolution of physician and beneficiary inquiries regarding the shipment of drugs and to establish a grievance process for the resolution of disputes. For disputes that are not resolved at the bidding entity, we propose to establish a national ombudsman to oversee and review complaints under the competitive acquisition program.

### 3. Bidding Process

*a. Evaluation of bids.*

We propose to select one or more winning bidders for each category based on the bid prices for the drugs, the ability to ensure product integrity, customer service, and past experience in the distribution of drugs. We also propose to reject any bid that we estimate would result in aggregate payments that exceed the payments that would have been made if the drugs in the category were paid at the ASP.

*b. Timing of bidding process.*

We expect to have the initial bidding process complete and the winning entities selected in time for the competitive acquisition program to be implemented for oncology drugs beginning in 2005 and non-oncology drugs beginning in 2006. We propose to select subsequent contractors on a

periodic basis and seek comment on the appropriate time between bidding periods and the appropriate length of the contracts.

*c. Bid prices.*

The prices bid by an entity would be the prices in effect and available for the supply of contracted drugs in the area through the entity for the entire contract period. The bid price would not vary within a competitive acquisition area. The bid price would include all costs related to carrying out the contract provisions, including costs related to the delivery, dispensing, and shipping of the drug.

*d. Bidding on a national or regional basis.*

We would propose, but not require, entities to bid for contracts in more than one competitive acquisition area.

### 4. Competitive Acquisition Areas

We seek comment on the appropriate geographic regions to establish for a competitive acquisition program.

### 5. Billing and Coinsurance Under Competitive Acquisition

We propose that a successful bidder would be responsible for billing Medicare and collecting coinsurance for the drugs they supply that are subsequently administered to Medicare beneficiaries.

### B. Average Sales Price

Under the competitive acquisition model option, a physician would make an annual election to obtain drugs in a given category through a winning bidder or could purchase the drugs and bill Medicare. If a physician chooses to purchase drugs, they would be paid under the ASP-based system described below. Manufacturers would be required to report the ASP to us on a quarterly basis.

#### 1. Definition of Average Sales Price

Under this proposed option we would propose to define the ASP for a drug for a quarter as a manufacturer's total sales for the quarter less any sales exempted from the ASP calculation divided by the total number of units of such drug sold by the manufacturer in such quarter less any units from sales exempted from the ASP calculation. We seek comment on this definition as well as on the appropriate categories of sales that should be exempted from the ASP calculation.

#### 2. Discounts

Under this proposal, in calculating the ASP, the manufacturer would take into account volume discounts, prompt pay discounts, cash discounts, the free

goods that are contingent on any purchase requirement, chargebacks, and rebates (other than rebates under section 1927), that result in a reduction of the cost to the purchaser. A rebate to a payor or other entity that does not take title to a covered outpatient drug shall not be taken into account in determining such price unless the manufacturer has an agreement with the payor or other entity under which the purchaser's price for the drug is reduced as a consequence of such rebate.

### 3. Payments.

We propose to pay for multi-source drugs at an appropriate markup above ASP and seek comment on a markup in the range of 101 to 112 percent of ASP. We propose to pay for single source drugs at the lesser of an appropriate markup of ASP in the range of 101 to 112 percent or the Wholesale Acquisition Cost (WAC).

*a. Wholesale Acquisition Cost (WAC).*

Under this competitive acquisition model option we would propose defining the WAC as the manufacturer's list price for the drug to wholesalers and direct purchasers in the United States as reported in wholesale price guides or other publications of drug pricing data. The WAC would not include prompt pay or other discounts, rebates or reductions in price.

### *B. Increases in Payments Related to the Costs of Furnishing or Administering Drugs*

As described earlier, section 429(b) of BIPA requires us to revise the Medicare payment methodology for drugs under section 1842(o) of the Act based on the GAO report to the Congress. Under section 429(b), to the extent the Secretary determines appropriate, the Secretary may make adjustments to the practice expense component of the physician fee schedule for costs incurred in the administration, handling, or storage of certain categories of such drugs and biologicals. Section 429(b) also authorizes the Secretary to make proposals for new payments to providers of services or suppliers for such costs, if appropriate. However, the estimated aggregate payments for drugs under the revised system (including additional payments for related costs of furnishing or administering the drug) cannot exceed payments as projected by the Secretary under the current system. Below, we discuss payment issues associated with furnishing or administering Medicare covered drugs. To the extent appropriate, we are proposing increased payments for the administration of drugs or new payments to providers or suppliers for