Pricing Under ASP

- Manufacturers submit quarterly ASP data by 11-digit National Drug Code (NDC)
- For multiple source drugs, the payment allowance limit for all drugs assigned to a billing code is 106 percent of the weighted average of the ASPs reported for the NDCs assigned to that billing code.
- For Single Source Drugs, the payment allowance limit is based on 106 percent of the Wholesaler Acquisition Cost (WAC), if less than the weighted average of the ASPs.

1847A Evaluation

- 1847A(6)(C):
  - (C) MULTIPLE SOURCE DRUG.—
    - (i) IN GENERAL.—The term “multiple source drug” means, for a calendar quarter, a drug for which there are 2 or more drug products which—
      - (I) are rated as therapeutically equivalent (under the Food and Drug Administration's most recent publication of “Approved Drug Products with Therapeutic Equivalence Evaluations”),
      - (II) except as provided in subparagraph (E), are pharmaceutically equivalent and bioequivalent, as determined under subparagraph (F) and as determined by the Food and Drug Administration, and
      - (III) are sold or marketed in the United States during the quarter.

1847A Evaluation

- 1847A(6)(C):
  - (ii) EXCEPTION.—With respect to single source drugs or biologicals that are within the same billing and payment code as of October 1, 2003, the Secretary shall treat such single source drugs or biologicals as if the single source drugs or biologicals were multiple source drugs.

1847A Evaluation

- 1847A(6)(D):
- SINGLE SOURCE DRUG OR BIOLOGICAL.—The term “single source drug or biological” means—
  - (i) a biological; or
  - (ii) a drug which is not a multiple source drug and which is produced or distributed under a new drug application approved by the Food and Drug Administration, including a drug product marketed by any cross-licensed producers or distributors operating under the new drug application.

Implementing ASP

- CMS is conducting a review to ensure that separate payment is made for single source drugs and biologics as required by the MMA.
- For the purposes of identifying “single source drugs” and “biological products” subject to payment under section 1847A, generally CMS will utilize a multi-step process. CMS will consider:
  - • The FDA approval,
  - • Therapeutic equivalents as determined by the FDA, and
  - • The date of first sale in the United States. 10/1/03 is very important.
- If satisfy these requirements, product must have its own ASP—examples of visco-supplements, IVIG and Albuterol.
- Possible legislative fix to the 10/1/03 exception.

OIG Work Plan--2008

- Computation of ASP—review of drug manufacturers' methodologies for computing the ASP and assess manufacturer compliance.
- Comparing ASP to WAMP and AMP—identify drugs that exceed 5% threshold.
- Changes in ASP Price for Part B drugs—review the extent to which ASPs for Medicare Part B drugs fluctuate from quarter to quarter.