Appendix A – Average Sales Price Reporting Data Elements

PROPOSED REVISIONS November 2008

CURRENT ASP DATA ELEMENTS:
Manufacturer's Name: Enter the reporting manufacturer's name.
11-Digit National Drug Code (NDC): Enter the full 11 digit NDC without dashes. Ensure reporting document is formatted to display leading zeros. Ensure the correct 5 digit labeler code is shown as the first 5 digits of the NDC.
Manufacturer's Average Sales Price (ASP): Enter ASP in $US rounded to 2 or more decimal places.
Number of ASP Units: Enter the number of 11-digit NDC packages sold.
Wholesale Acquisition Cost (WAC): Enter the WAC in effect on the last day of the reporting period for all single source drugs and biologicals. WAC is defined in Section 1847A(c)(6)(B) as "the manufacturer's list price for the drug or biological to wholesalers or direct purchasers in the United States, not including prompt pay or other discounts, rebates or reductions in price, for the most recent month for which the information is available, as reported in wholesale price guides or other publications of drug or biological pricing data." CMS further clarified, in 70 FR 70221, that manufacturers must report WAC for all single source drugs and biologicals (including new drugs) each reporting period. Manufacturers must report the WAC in effect on the last day of the reporting period.
Name of Drug or Biological: The trade or brand name of the product or the active ingredient name.
Strength of the Product: The dosage in one item (e.x., 250 mg tablet, 20 mg/ml solution, 1 I.U.)
Volume Per Item: The amount in one item. (ex., 10 ml in one vial, or 500 tablets in one bottle) Enter "1" for certain forms of drugs (e.g. powders and sheets) when "Strength of the Product" indicates the amount of the product per item.
Number of Items Per NDC: The number of items in the 11-digit NDC. (ex., For an NDC that has 4 vials in a shelf pack, the number of items per NDC is 4.)
Expiration Date of Last Lot Sold: Enter date in MM/DD/YY format. The expiration date of the last lot sold must be reported to CMS once at the end of utilization of the NDC or when there are no sales for three consecutive quarters. For ASP purposes, "at the end of utilization" means henceforth the manufacturer will not make sales of that NDC to any purchaser.
Date of First Sale: Enter date in MM/DD/YY format. Report for NDCs first sold on or after 04/01/06. Report at least once and no later than with the first ASP report.
Number of CAP units Excluded: Beginning with the 3Q2006 reporting period, report the number of whole or fractional units administered to a beneficiary by a Part B Drug Competitive Acquisition Program participating physician excluded from the ASP calculation.

PROPOSED ADDITIONAL ASP DATA ELEMENTS: REPORT THESE DATA ELEMENTS AT LEAST ONCE TO CMS.
FDA Application Number: Report the 6 digit application number assigned by the Food and Drug Administration (FDA). If more than one number is assigned, list all numbers. Use leading zeros if necessary to report 6 digits. Supplemental approval numbers are not required. If supplemental approval numbers are reported, use XXXXXX/XXXX format (6 digits for the approval number followed by a forward slash, then 4 digits for the supplemental approval number).
FDA Final Pre-Marketing Approval Date: Report the date in MM/DD/YY format. The FDA Final Pre-Marketing Approval Date is the date the FDA granted approval for the drug, biological or pre-marketing application. Enter the original approval date. Do not enter supplemental approval dates.
FDA Approval Type: Enter the type of FDA approval, such as NDA, ANDA, BLA, 510K, PMA, Vaccine, Human Tissue or Other (and specify the type).
Descriptive Data Corrected: Insert "Y" to indicate that a data element other than Manufacturer's ASP or Number of ASP Units has changed since the last report.