FAQ Results

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Question #4758: How does CMS calculate the Average Sales Price (ASP)-based payment limit?

Answers: For each billing code, CMS calculates a weighted average sales price using the Average Sales Price (ASP) data submitted by manufacturers. • Manufacturers submit ASP data at the 11-digit National Drug Code (NDC) level. • Manufacturers submit the number of units of the 11-digit NDC sold and the ASP for those units. • The number of billing units in an NDC is determined by the amount of drug in the package. For example: a manufacturer sells a box of 4 vials of a drug. Each vial contains 20 milligrams (mg). The billing code is per 10 mg. The number of billing units in this NDC for this billing code is (4 vials X 20 mg)/10 mg=8 billable units. Beginning April 1, 2008, CMS uses the following weighting methodology to determine the payment limit. • CMS sums the product of the manufacturer's ASP and the number of units of the 11-digit NDC sold for each NDC assigned to the billing and payment code, and then divides this total by the sum of the product of the number of units of the 11-digit NDC sold and the number of billing units in that NDC for each NDC assigned to the billing and payment code. • CMS weights the ASP for an NDC by the number of billing units sold for that NDC. Prior to April 1, 2008, the following weighting methodology applies. • CMS converts the manufacturer's ASP for each NDC into the average sales price per billing unit by dividing the manufacturer's ASP for that NDC by the number of billing units in that NDC. • CMS sums the product of the ASP per billing unit and the number of units of the 11-digit NDC sold for each NDC assigned to the billing code, and then divides this total by the sum of the number of units of the 11-digit NDC sold for each NDC assigned to the billing code. • CMS weights the ASP per billing units equally for each NDC regardless of package size.

Question #3303: Why do manufacturers have to report average sales prices to CMS?

Answers: The Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA) included several important provisions related to drug coverage and payment in the Medicare program. One of the provisions establishes a new Average Sales Price (ASP) payment system for the vast majority of Medicare Part B covered outpatient drugs and

biologicals not paid on a cost or prospective payment system basis. The new payment system requires quarterly reporting of manufacturers' ASPs for these drugs. Types of drugs subject to the ASP reporting requirement include those furnished incident to a physician's service, those furnished under the durable medical equipment (DME) benefit, certain oral anti-cancer drugs, and oral immunosuppressive drugs.

Question #3330: Will the ASP data submitted to CMS be releasable to the public?

Answers: As indicated in Section 1927(b)(3)(D) of the Act, as amended by MMA section 303(i)(4)(D), information disclosed by the manufacturer in connection with the requirement for ASP data submission is confidential and, not withstanding other laws, shall not be disclosed by the Secretary (or contractor therewith) in a form which discloses the identity of a specific manufacturer or wholesaler, prices charged for drugs by such manufacturer or wholesaler, except as necessary by the Secretary to carry out the provisions of section 1847A or 1847B of the Act, and to permit the Inspector General of the Department of Health and Human Services, the Comptroller General, and the Director of the Congressional Budget Office to review the information provided.

Question #3307: Who is required to submit ASP data?

Answers: Drug manufacturers are required to submit ASP data. The term manufacturer means any entity engaged in the following: • Production, preparation, propagation, compounding, conversion or processing of prescription drug product, either directly or indirectly by extraction from substances of natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis. • Packaging, repackaging, labeling, relabeling, or distribution of prescription drug products. Please note that the term manufacturer does not include a wholesale distributor of drugs or a retail pharmacy licensed under State law. However, manufacturers that also engage in wholesaler activities are required to report ASP data for those drugs that they manufacture.

Question #3321: Is a manufacturer required to report the wholesale acquisition cost (WAC) each reporting period?

Answers: Manufacturers must report wholesale acquisition cost (WAC) for all single source drugs (including new drugs) each reporting period. In submitting the WAC, manufacturers must report the WAC in effect on the last day of the reporting period. Further, manufacturers are required to report quarterly both the WAC and the Average Sales Price (ASP) for single source drugs, including new drugs, during the initial period (prior to submitting ASP based on a full quarter of sales).

Question #7763: Where can I find the latest average sales price (ASP) Medicare Part B payment files?

Answers: The payment file for the Medicare Part B drugs is updated quarterly and can be found on the CMS Average Sales Price (ASP) website, specifically at http://www.cms.hhs.gov/McrPartBDrugAvgSalesPrice/02_aspfiles.asp#TopOfPage.

Question Did CMS issue a regulation on the manufacturer submission of average sales price data?

#3304:

Answers: Yes. CMS issued the interim final rule titled "Manufacturer Submission of Manufacturer's Average Sales Price (ASP) Data for Medicare Part B Drugs and Biologicals." It was published on April 6, 2004 and is accessible on the CMS website at http://www.cms.hhs.gov/McrPartBDrugAvgSalesPrice/03_regulations.asp. Also available, is the September 16, 2004, final rule addressing the methodology for estimating price concessions known on a lagged basis.

Question #3312: How can a manufacturer report the Average Sales Price (ASP) of a drug if there are no sales of that drug?

Answers: The Average Sales Price (ASP) cannot be calculated if no units of the National Drug Code (NDC) are sold in that quarter. Manufacturers should report zero sales and Wholesale Acquisition Cost (WAC) (for single source drugs) for the NDC.

Question #3313: How should manufacturers account for returned goods in the calculation of ASP?

Answers: Our earlier response to this question was accessible on the CMS website beginning April 22, 2004. This earlier response indicated that manufacturers should subtract the value of the returns from the numerator of the ASP calculation and should subtract the number of units returned from the denominator. Based on public input, we are revising our response pending further review of this issue. Beginning with the data submission for sales during the third quarter of 2004, manufacturers should no longer subtract the value of the returns from the numerator of the ASP calculation and should no longer subtract the number of units returned from the denominator. In other words, the value of returns should not be included in the numerator and the number of returned units should not be included in the denominator when calculating the ASP for a reporting quarter.

Question #3308: Will physicians, hospitals, PBMs, and HMOs be required to report ASP data to CMS?

Answers: Only drug manufacturers as defined in section 1927(k)(5) of the Social Security Act are required to submit ASP data.

Question #3306: If a manufacturer has questions on Average Sales Price (ASP) reporting, how should they contact CMS?

Answers: Manufacturers can submit questions to the e-mail mailbox: Sec303ASPdata@cms.hhs.gov.

Question #3310: For the purposes of the Average Sales Price (ASP) calculation and reporting, is "unit" defined the same as under the Medicaid rebate program?

Answers: "Unit" is not defined the same as in the Medicaid rebate program. For the purposes of the Average Sales Price (ASP) calculation, ''unit'' is the product represented by the 11-digit National Drug Code (NDC). Beginning with the ASP reporting for the calendar quarter of July – Sept 2006, for the first three years of the Competitive Acquisition Program (CAP) for Part B Drugs and Biologicals, units of CAP drugs sold to approved CAP vendors

for use under the CAP are excluded from the ASP calculation.

Question #3328: After CMS receives the ASP data, how soon will the information be incorporated into the pricing file?

Answers: Timely and accurate data will be incorporated at the next available update. For example, the first quarter 2008 Medicare payment allowances will be based on the third quarter 2007 data submissions.

Question #3314: Should manufacturers include discounts given under the Medicare drug discount card program in their average sales price data submitted to CMS?

Answers: No, as consistent with the MMA, manufacturers should exclude prices negotiated for covered discount card drugs under an endorsed discount card program in calculating ASP data. Beginning in 2006 when the Medicare Part D prescription drug benefit is implemented, manufacturers should also exclude any prices negotiated by a prescription drug plan (including a Medicare Advantage plan) or by a qualified retiree prescription drug plan (as defined in section 1860D-22(a)(2)) on behalf of Part D eligible individuals.

Question #3329: Where should manufacturers submit their ASP data?

Answers: When sending ASP data to CMS via first class mail, federal express mail, or overnight delivery, please use the following address: Centers for Medicare & Medicaid Services Hospital and Ambulatory Policy Group Division of Ambulatory Services ATTN: Medicare ASP Data Mail Stop No. C4-01-26 7500 Security Boulevard Baltimore, MD 21244 Phone: 410-786-0548 Please include technical contact information for questions that may arise with the data submitted. Specifically, include the technical contact name, phone number, fax number, and e-mail address. Manufacturers requiring acknowledgment of our receipt of their diskette or CD-ROM data must include a stamped, self-addressed postcard or envelope with their submission. This postcard or envelope will be date stamped and returned but will only acknowledge receipt of the diskette, or CD-ROM data. If the ASP information is unreadable, is in the wrong format, is blank or, in any other way cannot be processed by us (e.g., virus), a phone call to the technical contact will be made. Diskettes or CD-ROMs will NOT be returned under ANY circumstances.

Question #8966: How will the Coordination of Benefits be administered between the local Medicare carrier, the CAP vendor's designated carrier, and the various Medigap insurers?

Answers: CAP will be the most successful when the physician, the beneficiary, the CAP vendor and the Medicare contractors work closely together on billing and other administrative concerns. We support this process through Medicare's existing Coordination of Benefits processes. In the Interim Final Rule (page 39052 of the Federal Register), we describe how this process provides for the automatic crossover of many Medicare beneficiaries' claims to their supplemental insurance provider after Medicare has paid its portion of the claim. For beneficiaries with supplemental insurance, their coinsurance obligation is usually met through this automatic coordination of benefit process, so that the beneficiary is not required to pay the coinsurance at the time of service. In addition, the CAP vendor would not have the burden of billing the supplemental insurance since this would happen automatically. The recently consolidated claims crossover process introduces standardization and efficiencies for the automatic crossover of claims to all participating supplemental insurers, including Medigap plans, employer retiree

supplemental plans, TRICARE, and State Medicaid Agencies, for their use in calculating their financial liability after Medicare. Under this consolidated crossover process, supplemental insurers execute a national Coordination of Benefits Agreement with a single CMS contractor, the national Coordination of Benefits Contractor (COBC), for purposes of receiving Medicare crossover claims. We expect that most supplemental insurers will participate in the national consolidated crossover process because of the consistencies and efficiencies that result from a standard national process. Participation by supplemental insurers will, in turn, result in standardization and efficiencies for suppliers, including CAP vendors, who seek reimbursement from these insurers.

Question #3316: What are nominal sales?

Answers: Nominal sales are defined as sales at a price less than 10 percent of the Average Manufacturer's Price as calculated under the Medicaid Rebate Program agreements.

Question #3324: Is there a specific format that manufacturers have to use in order to submit their Average Sales Price (ASP) to CMS?

Answers: Yes. Manufacturers should report the Average Sales Price (ASP) data to us using the Addendum A format in a Microsoft® Excel electronic file. Addendum A is accessible on the CMS website at http://www.cms.hhs.gov/McrPartBDrugAvgSalesPrice/01_overview.asp data is reported at the 11-digit National Drug Code level.

Question #3323: Can manufacturers make assumptions with respect to a particular aspect of the Average Sales Price (ASP) calculation in the absence of specific guidance in the Social Security Act or Federal regulations?

Answers: In the absence of specific guidance in the Social Security Act or Federal regulations, the manufacturer may make reasonable assumptions in its calculations of Average Sales Price (ASP), consistent with the general requirements and the intent of the Social Security Act, Federal Regulations, and its customary business practices. These assumptions should be submitted along with the ASP data and the signed certification form.

Question #7764: How often is the average sales price (ASP) NDC-HCPCS Crosswalk file updated?

Answers: Quarterly. The crosswalk is posted on the same website as the Medicare Part B drugs payment files at http://www.cms.hhs.gov/McrPartBDrugAvgSalesPrice/02_aspfiles.asp#TopOfPage