| CMS Manual System | **Department of Health & Human Services (DHHS)** |
|---|---|
| Pub 100-04 Medicare Claims Processing | **Centers for Medicare & Medicaid Services (CMS)** |
| **Transmittal 1513** | **Date: MAY 23, 2008** |
| | **Change Request 5798** |

**SUBJECT: Average Sales Price Updates**

**I. SUMMARY OF CHANGES:** This document furnishes you with updates and additions to language relating to the average sales price (ASP) drug pricing and payment methodology. These updates and additions manualize the instruction on the pricing as well as payment of ASP drugs, as stated in Section 303(c) of the Medicare Modernization Act of 2003 (MMA), and Section 1847A of the Social Security Act.

**New / Revised Material**
**Effective Date: June 23, 2008**
**Implementation Date: June 23, 2008**

*Disclaimer for manual changes only: The revision date and transmittal number apply only to red italicized material. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.*

**II. CHANGES IN MANUAL INSTRUCTIONS:** (N/A if manual is not updated)
R=REVISED, N=NEW, D=DELETED-*Only One Per Row.*

| R/N/D | Chapter / Section / Subsection / Title |
|---|---|
| R | 17/20/20.1/MMA Drug Pricing - Average Sales Price (ASP) |
| N | 17/20/20.1.2/Average Sales Price (ASP) Payment Methodology |
| N | 17/20/20.1.3./Exceptions to Average Sales Price (ASP) Payment Methodology |

**III. FUNDING:**
SECTION A: For Fiscal Intermediaries and Carriers:
No additional funding will be provided by CMS; Contractor activities are to be carried out within their operating budgets.

SECTION B: For Medicare Administrative Contractors (MACs):
The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

**IV. ATTACHMENTS:**

**Business Requirements**

**Manual Instruction**

**Unless otherwise specified, the effective date is the date of service.*

# Attachment - Business Requirements

| Pub. 100-04 | Transmittal: 1513 | Date: May 23, 2008 | Change Request: 5798 |
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**SUBJECT: Average Sales Price Updates**

**Effective Date**: June 23, 2008

**Implementation Date:** June 23, 2008

## I. GENERAL INFORMATION

**A. Background:** This document furnishes you with updates and additions to language relating to the Average Sales Price (ASP) drug pricing and payment methodology. These updates and additions manualize the instruction on the pricing as well as payment of ASP drugs, as stated in Section 303(c) of the Medicare Modernization Act of 2003 (MMA), and Section 1847A of the Social Security Act.

**B. Policy:** Section 303(c) of the Medicare Modernization Act of 2003 (MMA) revised the payment methodology for Part B covered drugs and biologicals that are not priced on a cost or prospective payment basis. In addition, these updates address how CMS has operationalized the terms "single source drug," "multiple source drug," and "biological product" in the context of payment under Section 1847A, as well as exceptions to payment methodology.

## II. BUSINESS REQUIREMENTS TABLE

*Use"Shall" to denote a mandatory requirement*

| Number | Requirement | Responsibility (place an "X" in each applicable column) | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | A/B MAC | DME MAC | FI | CARRIER | RHHI | Shared-System Maintainers | | | | OTHER |
| | | | | | | | FISS | MCS | VMS | CWF | |
| 5798.1 | Contractors shall follow the updated and new guidelines established that relate to ASP pricing, payment methodology, and exceptions, as stated in Chapter 17, §20 of the Medicare Claims Processing Manual. | X | X | X | X | | | | | | |
| 5798.1.1 | FIs and carriers must accept the ASP files made available by CMS for pricing bills/claims for any drug identified on the price files. | X | X | X | X | | | | | | |
| 5798.1.2 | The ASP drug pricing file shall contain 3 places after the decimal point in the currency field for the ASP file and contractors shall load the ASP file including 3 places after the decimal point. Contractors shall carry 3 places after the decimal point for the calculation of the amount due for a line item for each covered drug, | X | X | X | X | | | | | | |

| Number | Requirement | Responsibility (place an "X" in each applicable column) | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | A/B MAC | DME MAC | FI | CARRIER | RHHI | Shared-System Maintainers | | | | OTHER |
| | | | | | | | FISS | MCS | VMS | CWF | |
| | then follow standard rounding procedures in determining the final allowance for that line item. The final allowed amounts will continue to carry 2 places after the decimal point. | | | | | | | | | | |
| 5798.1.3 | The payment limits included in revised ASP and Not Otherwise Classified (NOC) payment files supersede the payment limits for these codes in any publication published prior to this document. | X | X | X | X | | | | | | |
| 5798.1.4 | The vast majority of drugs and biologicals not priced on a cost or prospective payment basis will be priced based on the average sales price (ASP) methodology. | X | X | X | X | | | | | | |
| 5798.1.5 | Pricing for compounded drugs is performed by the local contractor. | X | X | X | X | | | | | | |
| 5798.1.6 | ESRD drugs furnished by both independent and hospital-based ESRD facilities, as well as specified covered outpatient drugs, and drugs and biologicals with pass-through status under the Outpatient Prospective Payment System (OPPS), will be priced based on the ASP methodology. | X | X | X | X | | | | | | |
| 5798.1.7 | The payment allowance limits for Medicare Part B drugs and biologicals that are not paid on a cost or prospective payment basis are 106 percent of the ASP. | X | X | X | X | | | | | | |
| 5798.1.8 | The payment allowance limits for ESRD drugs when separately billed by freestanding and hospital-based ESRD facilities, as well as specified covered outpatient drugs, and drugs and biologicals with pass-through status under the OPPS, will be paid based on 106 percent of the ASP. | X | X | X | X | | | | | | |
| 5798.1.9 | For the purposes of identifying "single source drugs" and "biological products" subject to payment under Section 1847A, generally CMS (and its contractors) will utilize a multi-step process, as noted in the manual. | X | X | X | X | | | | | | |
| 5798.1.10 | The payment limit for a biological product or single source drug will be based on the pricing information for products marketed or sold under the applicable FDA approval. | X | X | X | X | | | | | | |
| 5798.1.11 | The payment allowance limits for blood and blood products not paid on a cost or prospective payment basis are 95 percent of the average wholesale price (AWP) as reflected in the published compendia. | X | X | X | X | | | | | | |

| Number | Requirement | Responsibility (place an "X" in each applicable column) | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | A/B MAC | DME MAC | FI | CARRIER | RHHI | Shared-System Maintainers | | | | OTHER |
| | | | | | | | FISS | MCS | VMS | CWF | |
| 5798.1.12 | The payment allowance limits for infusion drugs furnished through a covered item of durable medical equipment will continue to be 95 percent of the AWP reflected in the published compendia of October 1, 2003, unless the drug is compounded or the drug is furnished incident to a professional service. The payment allowance limits for infusion drugs furnished through a covered item of durable medical equipment that were not listed in the published compendia are 95 percent of the first published AWP unless the drug is compounded or the drug is furnished incident to a professional service. | X | X | X | X | | | | | | |
| 5798.1.13 | The payment allowance limits for influenza, Pneumococcal and Hepatitis B vaccines are 95 percent of the AWP as reflected in the published compendia except where the vaccine is furnished in a hospital outpatient department. Where the vaccine is administered in the hospital outpatient department, the vaccine is paid at reasonable cost. | X | X | X | X | | | | | | |
| 5798.1.14 | The payment allowance limits for drugs and biologicals that are not included in the ASP Medicare Part B Drug Pricing File or Not Otherwise Classified (NOC) Pricing File, other than new drugs that are produced or distributed under a new drug application (or other application) approved by the Food and Drug Administration, are based on the published wholesale acquisition cost (WAC) or invoice pricing, except under OPPS where the payment allowance limit is 95 percent of the published AWP. In determining the payment limit based on WAC, the contractors follow the methodology specified in Pub. 100-04, Chapter 17, Drugs and Biologicals, for calculating the AWP but substitute WAC for AWP. The payment limit is 100 percent of the lesser of the lowest-priced brand or median generic WAC. | X | X | X | X | | | | | | |
| 5798.1.15 | Carriers/DME MACs/SADMERC shall develop payment allowance limits for covered drugs when CMS does not supply the payment allowance limit on the ASP drug pricing file. At the contractors' discretion, contractors may contact CMS to obtain | X | X | X | X | | | | | | |

| Number | Requirement | Responsibility (place an "X" in each applicable column) | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | A/B MAC | DME MAC | FI | CARRIER | RHHI | Shared-System Maintainers | | | | OTHER |
| | | | | | | | FISS | MCS | VMS | CWF | |
| | payment limits for drugs not included in the quarterly ASP or NOC files or otherwise made available by CMS on the CMS Web site. If the payment limit is available from CMS, contractors will substitute CMS-provided payment limits for pricing based on WAC or invoice pricing. | | | | | | | | | | |
| 5798.1.16 | The payment allowance limits for new drugs and biologicals that are produced or distributed under a new drug application (or other new application) approved by the Food and Drug Administration and that are not included in the ASP Medicare Part B Drug Pricing File or Not Otherwise Classified (NOC) Pricing File are based on 106 percent of the WAC, or invoice pricing if the WAC is not published, except under OPPS where the payment allowance limit is 95 percent of the published AWP. This policy applies only to new drugs that were first sold on or after January 1, 2005. At the contractors' discretion, contractors may contact CMS to obtain payment limits for new drugs not included in the quarterly ASP or NOC files or otherwise made available by CMS on the CMS Web site. If the payment limit is available from CMS, contractors will substitute CMS-provided payment limits for pricing based on WAC or invoice pricing. | X | X | X | X | | | | | | |
| 5798.1.17 | The payment allowance limits for radiopharmaceuticals are not subject to ASP. Contractors should determine payment limits for radiopharmaceuticals based on the methodology in place as of November 2003 in the case of radiopharmaceuticals furnished in other than the hospital outpatient department. Radiopharmaceuticals furnished in the hospital outpatient department are paid charges reduced to cost by the hospital's overall cost to charge ratio. | X | X | X | X | | | | | | |

## III. PROVIDER EDUCATION TABLE

| Number | Requirement | Responsibility (place an "X" in each applicable column) |
|---|---|---|

| | | A/B MAC | DME MAC | FI | CARRIER | RHHI | Shared-System Maintainers | | | | OTHER |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | FISS | MCS | VMS | CWF | |
| 5798.2 | A provider education article related to this instruction will be available at http://www.cms.hhs.gov/MLNMattersArticles/ shortly after the CR is released. You will receive notification of the article release via the established "MLN Matters" listserv.<br>Contractors shall post this article, or a direct link to this article, on their Web site and include information about it in a listserv message within one week of the availability of the provider education article. In addition, the provider education article shall be included in your next regularly scheduled bulletin. Contractors are free to supplement MLN Matters articles with localized information that would benefit their provider community in billing and administering the Medicare program correctly. | X | X | X | X | | | | | | |

## IV. SUPPORTING INFORMATION

**A. For any recommendations and supporting information associated with listed requirements, use the box below:**
*Use "Should" to denote a recommendation.*

| X-Ref Requirement Number | Recommendations or other supporting information: |
|---|---|
| Sec. 303(c)<br>Sec. 1847A | Medicare Modernization Act of 2003 (MMA)<br>Social Security Act |

## V. CONTACTS

**Pre-Implementation Contact(s):** Glenn McGuirk, (410) 786-5723, Glenn.McGuirk@cms.hhs.gov

**Post-Implementation Contact(s):** Glenn McGuirk, (410) 786-5723, Glenn.McGuirk@cms.hhs.gov

## VI. FUNDING

**A. *For Fiscal Intermediaries and Carriers, use only one of the following statements:***

No additional funding will be provided by CMS; contractor activities are to be carried out within their operating budgets.

**B.** ***For Medicare Administrative Contractors (MACs),*** **use the following statement:**

The contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the Statement of Work (SOW). The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

# Medicare Claims Processing Manual
## Chapter 17 - Drugs and Biologicals

**Table of Contents**

***(Rev. 1513, 05-23-08)***

**Transmittals for Chapter 17**
Crosswalk to Old Manuals

*20.1.2 - Average Sales Price (ASP) Methodology*
*20.1.3 - Exceptions to Average Sales Price (ASP) Payment Methodology*

## 20.1 – MMA Drug Pricing – Average Sales Price (ASP)

***(Rev. 1513; Issued: 05-23-08; Effective/Implementation Date: 06-23-08)***

In general, CMS establishes a single, national payment limit for FI, carrier, *DME MAC, and A/B MAC* payment for each Medicare-covered drug whose payment is determined based on the methodology described above. Drugs billed to *DME MACs* are still priced locally, albeit under the new statutory formula, as applicable. The four DME MACs jointly establish drug payment limits for drugs that are billed to *DME MACs.*

The CMS provides an ASP file to each FI, carrier, *DME MAC, and A/B MAC* for pricing drugs. Each FI, carrier, *DME MAC, and A/B MAC* must accept the ASP files made available by CMS for pricing bills/claims for any drug identified on the price files.

The ASP drug pricing file shall contain 3 places after the decimal point in the currency field for the ASP file and contractors shall load the ASP file including 3 places after the decimal point. Contractors shall carry 3 places after the decimal point for the calculation of the amount due for a line item for each covered drug, then follow standard rounding procedures in determining the final allowance for that line item. The final allowed amounts will continue to carry 2 places after the decimal point.

*The payment limits included in the revised ASP and Not Otherwise Classified (NOC) payment files supersede the payment limits for these codes in any publication published prior to this document*.

### *20.1.2 –Average Sales Price (ASP) Payment Methodology*

***(Rev. 1513; Issued: 05-23-08; Effective/Implementation Date: 06-23-08)***

*Section 303(c) of the Medicare Modernization Act of 2003 (MMA) revised the payment methodology for Part B covered drugs and biologicals that are not priced on a cost or prospective payment basis. Per the MMA, beginning January 1, 2005, the vast majority of drugs and biologicals not priced on a cost or prospective payment basis will be priced based on the average sales price (ASP) methodology. Pricing for compounded drugs is performed by the local contractor. Additionally, beginning in 2006, all ESRD drugs furnished by both independent and hospital-based ESRD facilities, as well as specified covered outpatient drugs, and drugs and biologicals with pass-through status under the Outpatient Prospective Payment System (OPPS), will be priced based on the ASP methodology. The ASP methodology is based on quarterly data submitted to CMS by manufacturers. CMS will supply contractors with the ASP drug pricing files for Medicare Part B drugs on a quarterly basis. Contractors will be notified of the availability of this file via a Recurring Update Notification. Please click here to see these notifications.*

*The absence or presence of a HCPCS code and its associated payment limit does not indicate Medicare coverage of the drug or biological. Similarly, the inclusion of a payment limit within a specific column does not indicate Medicare coverage of the drug in that specific category. The local Medicare contractor processing the claim shall make these determinations.*

*Beginning January 1, 2005, in general, the payment allowance limits for Medicare Part B drugs and biologicals that are not paid on a cost or prospective payment basis are 106 percent of the ASP. Beginning January 1, 2006, in general, the payment allowance limits for ESRD drugs when separately billed by freestanding and hospital-based ESRD facilities, as well as specified covered outpatient drugs, and drugs and biologicals with pass-through status under the OPPS, will be paid based on 106 percent of the ASP. CMS will update the payment allowance limits quarterly.*

*As announced in late 2006, CMS has been working further to ensure that accurate and separate payment is made for single source drugs and biologicals as required by Section 1847A of the Social Security Act. As part of this effort, we have also reviewed how we have operationalized the terms "single source drug," "multiple source drug," and "biological product" in the context of payment under Section 1847A. For the purposes of identifying "single source drugs" and "biological products" subject to payment under Section 1847A, generally CMS (and its contractors) will utilize a multi-step process. We will consider:*

- *The FDA approval;*
- *Therapeutic equivalents as determined by the FDA; and*
- *The date of first sale in the United States.*

*For a biological product (as evidenced by a new FDA Biologic License Application or other relevant FDA approval) or a single source drug (that is, not a drug for which there are two or more drug products that are rated as therapeutically equivalent in the most recent FDA Orange Book) first sold in the United States after October 1, 2003, the payment limit for a biological product or single source drug will be based on the pricing information for products marketed or sold under the applicable FDA approval. As appropriate, a unique HCPCS code will be assigned to facilitate separate payment. Separate payment may be operationalized through use of "not otherwise classified" HCPCS codes.*

## *20.1.3 – Exceptions to Average Sales Price (ASP) Payment Methodology*

***(Rev. 1513; Issued: 05-23-08; Effective/Implementation Date: 06-23-08)***

*The payment allowance limits for blood and blood products (other than blood clotting factors) that are not paid on a reasonable charge or prospective payment basis, are determined in the same manner the payment allowance limits were determined on October 1, 2003. Specifically, the payment allowance limits for blood and blood products are 95 percent of the average wholesale price (AWP) as reflected in the published compendia. The payment allowance limits will be updated on a quarterly basis. Blood and blood products furnished in the hospital outpatient department are paid under OPPS at the amount specified for the Ambulatory Payment Classification (APC) to which the product is assigned.*

*The payment allowance limits for infusion drugs furnished through a covered item of durable medical equipment on or after January 1, 2005, will continue to be 95 percent of the AWP reflected in the published compendia as of October 1, 2003, unless the drug is compounded or the drug is furnished incident to a professional service. The payment allowance limits for*

*infusion drugs furnished through a covered item of durable medical equipment that were not listed in the published compendia as of October 1, 2003, (i.e., new drugs) are 95 percent of the first published AWP unless the drug is compounded or the drug is furnished incident to a professional service.*

*The payment allowance limits for influenza, Pneumococcal and Hepatitis B vaccines are 95 percent of the AWP as reflected in the published compendia except where the vaccine is furnished in a hospital outpatient department. Where the vaccine is administered in the hospital outpatient department, the vaccine is paid at reasonable cost. CMS will supply contractors with the payment allowance limits annually to be effective on September 1 of each year. Contractors will be notified of the availability of this file via a Recurring Update Notification. Please click here to see these notifications.*

*The payment allowance limits for drugs and biologicals that are not included in the ASP Medicare Part B Drug Pricing File or Not Otherwise Classified (NOC) Pricing File, other than new drugs that are produced or distributed under a new drug application (or other application) approved by the Food and Drug Administration, are based on the published Wholesale Acquisition Cost (WAC) or invoice pricing, except under OPPS where the payment allowance limit is 95 percent of the published AWP. In determining the payment limit based on WAC, the contractors follow the methodology specified in Pub. 100-04, Chapter 17, Drugs and Biologicals, for calculating the AWP, but substitute WAC for AWP. The payment limit is 100 percent of the lesser of the lowest-priced brand or median generic WAC.*

*Carriers, DME MACs, and A/B MACs shall develop payment allowance limits for covered drugs when CMS does not supply the payment allowance limit on the ASP drug pricing file. At the contractors' discretion, contractors may contact CMS to obtain payment limits for drugs not included in the quarterly ASP or NOC files or otherwise made available by CMS on the CMS Web site. If the payment limit is available from CMS, contractors will substitute CMS-provided payment limits for pricing based on WAC or invoice pricing. CMS will provide the payment limits either directly to the requesting contractor or via posting an MS Excel file on the CMS Web site.*

*The payment allowance limits for new drugs and biologicals that are produced or distributed under a new drug application (or other new application) approved by the Food and Drug Administration, and that are not included in the ASP Medicare Part B Drug Pricing File or Not Otherwise Classified (NOC) Pricing File, are based on 106 percent of the WAC, or invoice pricing if the WAC is not published, except under OPPS where the payment allowance limit is 95 percent of the published AWP. This policy applies only to new drugs that were first sold on or after January 1, 2005. At the contractors' discretion, contractors may contact CMS to obtain payment limits for new drugs not included in the quarterly ASP or NOC files or otherwise made available by CMS on the CMS Web site. If the payment limit is available from CMS, contractors will substitute CMS-provided payment limits for pricing based on WAC or invoice pricing. CMS will provide the payment limits either directly to the requesting contractor or via posting an MS Excel file on the CMS Web site.*

*The payment allowance limits for radiopharmaceuticals are not subject to ASP. Carriers should determine payment limits for radiopharmaceuticals based on the methodology in place as of November 2003 in the case of radiopharmaceuticals furnished in other than the hospital*

*outpatient department. Please refer to Chapter 17, §90.2 of the manual regarding radiopharmaceuticals furnished in the hospital outpatient department.*