# **CMS Manual System**

# **Pub 100-04 Medicare Claims Processing**

**Transmittal 876** 

**Department of Health & Human Services (DHHS)** 

Centers for Medicare & Medicaid Services (CMS)

Date: FEBRUARY 24, 2006 Change Request 4319

SUBJECT: April 2006 Quarterly Average Sales Price (ASP) Medicare Part B Drug Pricing File and Revisions to January 2005, April 2005, July 2005, October 2005, and January 2006 Quarterly ASP Medicare Part B Drug Pricing Files

**I. SUMMARY OF CHANGES:** This Change Request provides information on the payment allowance limits for Medicare Part B drugs, effective April 1, 2006 through June 30, 2006, as well as revised payment files for the January 2005, April 2005, July 2005, October 2005, and January 2006 Quarterly ASP Medicare Part B Drug Pricing Files.

### **NEW/REVISED MATERIAL:**

**EFFECTIVE DATE: April 1, 2006** 

**IMPLEMENTATION DATE: April 3, 2006** 

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
N/A	

#### III. FUNDING:

No additional funding will be provided by CMS; contractor activities are to be carried out within their FY 2006 operating budgets.

### IV. ATTACHMENTS:

Recurring Update Notification

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

# **Attachment – Recurring Update Notification**

Pub. 100-04 | Transmittal: 876 | Date: February 24, 2006 | Change Request 4319

SUBJECT: April 2006 Quarterly Average Sales Price (ASP) Medicare Part B Drug Pricing File and Revisions to January 2005, April 2005, July 2005, October 2005, and January 2006 Quarterly ASP Medicare Part B Drug Pricing Files

### I. GENERAL INFORMATION

- A. Background: Section 303(c) of the Medicare Modernization Act of 2003 (MMA) revises the payment methodology for Part B covered drugs that are not paid on a cost or prospective payment basis. Per the MMA, beginning January 1, 2005, drugs and biologicals not paid on a cost or prospective payment basis will be paid based on the average sales price (ASP) methodology. Additionally, 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 OPPS, will be paid 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.
- **B.** Policy: Beginning January 1, 2005, 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, the payment allowance limits for all 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. There are exceptions to this general rule as summarized below.
- (1) The payment allowance limits for blood and blood products (other than blood clotting factors), 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.
- (2) 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, regardless of whether or not the durable medical equipment is implanted. The payment allowance limits will not be updated in 2006. 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.
- (3) The payment allowance limits for influenza, Pneumococcal and Hepatitis B vaccines are 95 percent of the AWP as reflected in the published compendia.
- (4) The payment allowance limits for drugs 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 approved by the Food and Drug Administration, are based on the published wholesale acquisition cost (WAC) or invoice pricing. In determining the payment limit based on WAC, the contractors follow the methodology specified in Chapter 17, Drugs and Biologicals, of the Medicare Claims Processing Internet Only Manual for calculating the Average Wholesale Price (AWP) but substitute WAC for AWP. The payment limit is 100 percent of the lesser of the lowest brand or median generic WAC. 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.

- (5) The payment allowance limits for new drugs that are produced or distributed under a new drug 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. This policy applies only to new drugs that were sold on or after January 1, 2005.
- (6) 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.

On or after March 20, 2006, revised January 2005, April 2005, July 2005, October 2005, January 2006 ASP and NOC payment files, and the new April 2006 ASP and NOC files will be available for download. The revised January 2005 payment allowance limits apply to dates of service January 1, 2005 through March 31, 2005. The revised April 2005 payment allowance limits apply to dates of service April 1, 2005 through June 30, 2005. The revised July 2005 payment allowance limits apply to dates of service July 1, 2005 through September 30, 2005. The revised October 2005 payment allowance limits apply to dates of service January 1, 2006 through March 31, 2006. The April 2006 payment allowance limits apply to dates of service April 1, 2006 through June 30, 2006.

The payment limits included in the revised ASP and NOC payment files supersede the payment limits for these codes in any publication published prior to this document.

**NOTE:** 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.

### II. BUSINESS REQUIREMENTS

Number

"Shall" denotes a mandatory requirement "Should" denotes an optional requirement

Requirement	Requirements	Responsibility ("X" indicates the

columns that apply)

	F I		R H	Ca	D M E		red S intain	Syste ners	em	Other
			H I			F I S S	M C S	V M S	C W F	
4319.1	The April 2006 and revised January 2005, April 2005, July 2005, October 2005, and January 2006 ASP drug pricing files for Medicare Part B drugs will be available via the CMS Data Center (CDC).	X	X	X	X	X	X	X		
4319.1.1	Contractors shall download the revised January 2005 ASP drug pricing file through the CDC on or after March 20, 2006. Final File:  MU00.@BF12390.ASP.CY05B.JAN.V0320	X	X	X	X	X	X	X		
4319.1.2	Contractors shall overlay the previous January 2005 file with the new January 2005 ASP drug pricing file.	X	X	X	X	X	X	X		
4319.1.3	Contractors shall use the revised January 2005 ASP and NOC drug pricing files to pay for Medicare Part B drugs effective January 1, 2005 through March 31, 2005.	X	X	X	X	X	X	X		
4319.1.4	Contractors shall download the revised April 2005 ASP drug pricing file through the CDC on or after March 20, 2006. Final File:  MU00.@BF12390.ASP.CY05B.APR.V0320	X	X	X	X	X	X	X		
4319.1.5	Contractors shall overlay the previous April 2005 file with the new April 2005 ASP drug pricing file.	X	X	X	X	X	X	X		
4319.1.6	Contractors shall use the revised April 2005 ASP and NOC drug pricing files to pay for Medicare Part B drugs effective April 1, 2005 through June 30, 2005.	X	X	X	X	X	X	X		
4319.1.7	Contractors shall download the revised July 2005 ASP drug pricing file through the CDC on or after March 20, 2006. Final File: MU00.@BF12390.ASP.CY05B.JUL.V0320	X	X	X	X	X	X	X		

Requirement Number	Requirements	Responsibility ("X" indicates the columns that apply)				es the					
Tumber		F	R H	C	D M	Sha	red S intai		m	Other	
		H r I r i		I r		E R C	F I S	M C S	V M S		
4319.1.8	Contractors shall overlay the previous July 2005 file with the new July 2005 ASP drug pricing file.	X	X	X	X	X	X	X			
4319.1.9	Contractors shall use the revised July 2005 ASP and NOC drug pricing files to pay for Medicare Part B drugs effective July 1, 2005 through September 30, 2005.	X	X	X	X	X	X	X			
4319.1.10	Contractors shall download the revised October 2005 ASP drug pricing file through the CDC on or after March 20, 2006. Final File:  MU00.@BF12390.ASP.CY05B.OCT.V0320	X	X	X	X	X	X	X			
4319.1.11	Contractors shall overlay the previous October 2005 file with the new October 2005 ASP drug pricing file.	X	X	X	X	X	X	X			
4319.1.12	Contractors shall use the revised October 2005 ASP and NOC drug pricing files to pay for Medicare Part B drugs effective October 1, 2005 through December 31, 2005.	X	X	X	X	X	X	X			
4319.1.13	Contractors shall download the revised January 2006 ASP drug pricing file through the CDC on or after March 20, 2006. Final File:  MU00.@BF12390.ASP.CY06.JAN.V0320	X	X	X	X	X	X	X			
4319.1.14	Contractors shall overlay the previous January 2006 file with the new January 2006 ASP drug pricing file.	X	X	X	X	X	X	X			
4319.1.15	Contractors shall use the revised January 2006 ASP and NOC drug pricing files to pay for Medicare Part B drugs effective January 1, 2006 through March 31, 2006.	X	X	X	X	X	X	X			

Requirement Number	Requirements	Responsibility ("X" indicates the columns that apply)				es the				
Tunibei		F	R	C	D	Sha	red S		em	Other
		I	H	a r	M E	Ma	intai	ners		
			I	r i e r	R C	F I S S	M C S	V M S	C W F	
4319.1.16	Contractors shall download the new April 2006 ASP drug pricing file through the CDC on or after March 20, 2006. Final File: MU00.@BF12390.ASP.CY06.APR.V0320	X	X	X	X	X	X	X		
4319.2	Contractors shall not search and adjust claims that have already been processed unless brought to their attention.	X	X	X	X	X	X	X		
4319.3	Notification of successful receipt shall be sent via e-mail to price_file_receipt@cms.hhs.gov stating the name of the file received and the entity for which it was received (e.g., carrier/DMERC/fiscal intermediary name and number).	X	X	X	X	X	X	X		
4319.4	The ASP and NOC drug pricing files will contain the applicable payment allowance limits (i.e., 106% ASP, 106% WAC, or 95% AWP); therefore, no additional payment calculation is required by the Medicare contractors.	X	X	X	X	X	X	X		
4319.5	For any drug or biological not listed in the ASP or NOC drug pricing files, contractors shall determine the payment allowance limits in accordance with the policy described in this CR, and FIs should seek payment allowances from their local carrier.	X	X	X	X	X	X	X		
4319.6	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 shall substitute CMS-provided payment limits for pricing based on WAC or invoice pricing.	X	X	X	X	X	X	X		

Requirement Number	Requirements	Responsibility ("X" indicates the columns that apply)								
Tumber		F I	R H	C a	D M	Sha	red S intain		em	Other
			H I	r r i e r	E R C	F I S	M C S	V M S	C W F	
	Contractors shall contact CMS via E-mail at <a href="mailto:Sec303ASPdata@cms.hhs.gov">Sec303ASPdata@cms.hhs.gov</a> . Contractors shall include "Pricing Request" in the subject line.									
4319.7	Contractors shall use the Medicare Contractor Reporting Template for Part B drugs to report information on Medicare Part B drugs not paid on a cost or prospective payment basis when payment limits are not listed in the quarterly drug pricing ASP and NOC files, or in the OPPS Pricer.	X	X	X	X	X	X	X		
	The report shall list all drugs that were priced since the last submitted report. Reports should cover approximately 30 days of pricing activity. Drugs omitted from previous reports shall be reported in the next monthly report.									
4319.8.	Contractors shall use the template to report pricing information for the NOC drugs not included on the Medicare Part B NOC pricing file, any HCPCS drug codes not on the ASP file, and OPPS drugs not in the OPPS Pricer.	X	X	X	X	X	X	X		
4319.8.1	Carriers do not need to report radiopharmaceuticals.			X						
4319.8.2	Fiscal Intermediaries must report drugs, biologicals, and radiopharmaceuticals that are billed using C9399.	X								
4319.8.3	Contractors shall download the template from the CMS Web site at <a href="http://www.cms.hhs.gov/McrPartBDrugAvgSalesPrice/02_aspfiles.asp.">http://www.cms.hhs.gov/McrPartBDrugAvgSalesPrice/02_aspfiles.asp.</a>	X	X	X	X	X	X	X		

Requirement Number	Requirements	Responsibility ("X" indicates the columns that apply)								
		F I	R H H I	C a r r i e r	D M E R C	Shai	red S		С	Other
4319.8.4	Contractors shall complete the template monthly, which shall be in MS Excel format, to <a href="mailto:sec303aspdata@cms.hhs.gov">sec303aspdata@cms.hhs.gov</a> on the first business day of the month.	X	X	X	X	X	X	X		

### III. PROVIDER EDUCATION

Requirement Number	Requirements	Responsibility ("X" indicates the columns that apply)								
		F I	R H H	C a r	D M E	Ma	red S intair		m	Other
			I	r r i e r	R C	F I S S		V M S	C W F	
4319.9	A provider education article related to this instruction will be available at <a href="http://www.cms.hhs.gov/MedlearnMattersArticles/">http://www.cms.hhs.gov/MedlearnMattersArticles/</a> shortly after the CR is released. You will receive notification of the article release via the established "medlearn matters" listserv. 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 1 week of the availability of the provider education article. In addition, the provider education article shall be included in your next regularly scheduled bulletin and incorporated into any educational events on this topic. Contractors are free to supplement Medlearn 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 AND POSSIBLE DESIGN CONSIDERATIONS

## A. Other Instructions: N/A

X-Ref Requirement #	Instructions

B. Design Considerations: N/A

X-Ref Requirement #	Recommendation for Medicare System Requirements

C. Interfaces: N/A

D. Contractor Financial Reporting /Workload Impact: N/A

E. Dependencies: N/A

F. Testing Considerations: N/A

V. SCHEDULE, CONTACTS, AND FUNDING

Effective Date*: April 1, 2006	No additional funding will be
Implementation Date: April 3, 2006	provided by CMS; contractor activities are to be carried out within their FY 2006 operating
<b>Pre-Implementation Contact(s):</b> Jennifer Fan, 410-	budgets.
786-1100, Catherine Jansto, 410-786-7762, or	
Angela Mason, 410-786-7452.	
Post-Implementation Contact(s): Appropriate	
Regional Office	

<sup>\*</sup>Unless otherwise specified, the effective date is the date of service.