

<b>CMS Manual System</b>	<b>Department of Health &amp; Human Services (DHHS)</b>
<b>Pub 100-04 Medicare Claims Processing</b>	<b>Centers for Medicare &amp; Medicaid Services (CMS)</b>
<b>Transmittal 1795</b>	<b>Date: August 14, 2009</b>
	<b>Change Request 6585</b>

**SUBJECT: October 2009 Quarterly Average Sales Price (ASP) Medicare Part B Drug Pricing Files and Revisions to Prior Quarterly Pricing Files**

**I. SUMMARY OF CHANGES:** Section 303(c) of the Medicare Modernization Act of 2003 revised the payment methodology for Part B covered drugs and biologicals that are not paid on a cost or prospective payment basis. The vast majority of drugs and biologicals not paid on a cost or prospective payment basis are paid based on the average sales price (ASP) methodology. Pricing for compounded drugs is performed by the local contractor. The initial release of this RUN can be found in Chapter 17, section 20.1.

**New / Revised Material**

**Effective Date: October 1, 2009**

**Implementation Date: October 5, 2009**

*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:**

**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:**

**Recurring Update Notification**

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

# Attachment – Recurring Update Notification

Pub. 100-04	Transmittal: 1795	Date: August 14, 2009	Change Request 6585
-------------	-------------------	-----------------------	---------------------

**SUBJECT: October 2009 Quarterly Average Sales Price (ASP) Medicare Part B Drug Pricing Files and Revisions to Prior Quarterly Pricing Files**

**Effective Date:** October 1, 2009

**Implementation Date:** October 5, 2009

## I. GENERAL INFORMATION

**A. Background:** Section 303(c) of the Medicare Modernization Act of 2003 revised the payment methodology for Part B covered drugs and biologicals that are not paid on a cost or prospective payment basis. The vast majority of drugs and biologicals not paid on a cost or prospective payment basis are paid based on the average sales price (ASP) methodology. Pricing for compounded drugs is performed by the local contractor.

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. Payment allowance limits under the OPDS are incorporated into the Outpatient Code Editor (OCE) through separate instructions.

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.

**B. Policy:** In general, 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% of the ASP. Further, beginning January 1, 2006, payment allowance limits are paid based on 106% of the ASP for the following:

- ESRD drugs (when separately billed by freestanding and hospital-based ESRD facilities), and
- Specified covered outpatient drugs and drugs and biologicals with pass-through status under the OPDS.

Beginning January 1, 2008, under the OPPTS, payment allowance limits for specified covered outpatient drugs are paid at ASP+5%. Beginning January 1, 2009, under the OPPTS, payment allowance limits for specified covered outpatient drugs are paid at ASP+4%. Drugs and biologicals with pass-through status under the OPPTS continue to have a payment allowance limit of 106% of the ASP. CMS will update the payment allowance limits quarterly. There are exceptions to this general rule. These exceptions are stated in the Medicare Claims Processing Manual, Chapter 17, Section 20.1.3, Exceptions to Average Sales Price (ASP) Payment Methodology.

**Drugs Furnished During Filling or Refilling an Implantable Pump or Reservoir**

Physicians (or a practitioner described in Section 1842(b) (18) (C)) may be paid for filling or refilling an implantable pump or reservoir when it is medically necessary for the physician (or other practitioner) to perform the service. Contractors must find the use of the implantable pump or reservoir medically reasonable and necessary in order to allow payment for the professional service to fill or refill the implantable pump or reservoir and to allow payment for drugs furnished incident to the professional service. If a physician (or other practitioner) is prescribing medication for a patient with an implantable pump, a nurse may refill the pump if the medication administered is accepted as a safe and effective treatment of the patient’s illness or injury; there is a medical reason that the medication cannot be taken orally; and the skills of the nurse are needed to infuse the medication safely and effectively.

The payment methodology for drugs furnished incident to the filling or refilling of an implantable pump or reservoir is determined under the ASP methodology, as described above unless the drug furnished incident to the filling or refilling of an implantable pump or reservoir is a compounded drug, then pricing is performed by the local contractor.

**Quarterly Payment Files**

This Recurring Update addresses the following pricing files:

<b>Files</b>	<b>Effective Dates of Service</b>
October 2009 ASP and ASP NOC files	October 1, 2009, through December 31, 2009
July 2009 ASP and ASP NOC files	July 1, 2009, through September 30, 2009
April 2009 ASP and ASP NOC files	April 1, 2009, through June 30, 2009
January 2009 ASP and NOC Files	January 1, 2009, through March 31, 2009
October 2008 ASP and NOC Files	October 1, 2008, through December 31, 2008

**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 TABLE

Use "Shall" to denote a mandatory requirement

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A / B  M A C	D M E  M A C	F I	C A R R I E R	R H I	Shared-System Maintainers				OTHER
							F I S S	M C S	V M S	C W F	
6585.1	The October 2009 and, if released, the revised July 2009, April 2009, January 2009, and October 2008 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		
6585.1.1	Contractors shall download the October 2009 ASP drug pricing file through the CDC on or after September 17, 2009. Final File: <a href="http://MU00.@BF12390.ASP.R2.CY09.OCT.H.V0917">MU00.@BF12390.ASP.R2.CY09.OCT.H.V0917</a>	X	X	X	X	X	X		X		
6585.1.2	Contractors shall retrieve the October 2009 ASP NOC pricing file from the CMS ASP Web page on or after September 17, 2009.	X	X		X	X					
6585.1.3	Contractors shall use the October 2009 ASP and NOC drug pricing files to determine the payment limit for claims for separately payable Medicare Part B drugs processed or reprocessed on or after October 5, 2009 with dates of service October 1, 2009, through December 31, 2009.	X	X		X	X	X		X		
6585.1.3.1	Contractors shall use the October 2009 ASP drug pricing file to update the drug payment limits for claims for infusion drugs furnished through a covered item of DME processed or reprocessed on or after October 5, 2009 with dates of service on or after October 1, 2009.	X	X		X				X		
6585.1.4	This business requirement intentionally left blank.										
6585.1.5	If released by CMS, contractors shall download the revised July 2009 ASP drug pricing file through the CDC on or after September 17, 2009. Final File: <a href="http://MU00.@BF12390.ASP.R2.CY09.JUL.H.V0917">MU00.@BF12390.ASP.R2.CY09.JUL.H.V0917</a>	X	X	X	X	X	X		X		
6585.1.6	If released by CMS, contractors shall overlay	X	X	X	X	X	X		X		

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A / B  M A C	D M E  M A C	F I	C A R R I E R	R H H I	Shared-System Maintainers				OTHER
							F I S S	M C S	V M S	C W F	
	or manually update the previous July 2009 file with the new July 2009 ASP drug pricing file.										
6585.1.7	If released by CMS, contractors shall use the revised July 2009 ASP drug pricing file to determine the payment limit for claims for separately payable Medicare Part B drugs processed or reprocessed on or after October 5, 2009 with dates of service July 1, 2009, through September 30, 2009.	X	X	X	X	X	X		X		
6585.1.8	If released by CMS, contractors shall retrieve the revised July 2009 ASP NOC pricing file from the CMS ASP Web page on or after September 17, 2009.	X	X		X	X					
6585.1.9	If released by CMS, contractors shall use the revised July 2009 ASP NOC pricing file to determine the payment limit for claims for separately payable Medicare Part B drugs processed or reprocessed on or after October 5, 2009 with dates of service July 1, 2009, through September 30, 2009.	X	X		X	X	X		X		
6585.1.10	If released by CMS, contractors shall download the revised April 2009 ASP drug pricing file through the CDC on or after September 17, 2009. Final File: <a href="http://MU00.@BF12390.ASP.CY09.APR.H.V0917">MU00.@BF12390.ASP.CY09.APR.H.V0917</a>	X	X	X	X	X	X		X		
6585.1.11	If released by CMS, contractors shall overlay or manually update the previous April 2009 file with the new April 2009 ASP drug pricing file.	X	X	X	X	X	X		X		
6585.1.12	If released by CMS, contractors shall use the revised April 2009 ASP drug pricing file to determine the payment limit for claims for separately payable Medicare Part B drugs processed or reprocessed on or after October 5, 2009 with dates of service April 1, 2009, through June 30, 2009.	X	X	X	X	X	X		X		
6585.1.13	If released by CMS, contractors shall retrieve	X	X		X	X					

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A / B  M A C	D M E  M A C	F I	C A R R I E R	R H H I	Shared-System Maintainers				OTHER
							F I S S	M C S	V M S	C W F	
	the revised April 2009 ASP NOC pricing file from the CMS ASP Web page on or after September 17, 2009.										
6585.1.14	If released by CMS, contractors shall use the revised April 2009 ASP NOC pricing file to determine the payment limit for claims for separately payable Medicare Part B drugs processed or reprocessed on or after October 5, 2009 with dates of service April 1, 2009, through June 30, 2009.	X	X		X	X	X		X		
6585.1.15	If released by CMS, contractors shall download the revised January 2009 ASP drug pricing file through the CDC on or after September 17, 2009. Final File: <a href="mailto:MU00.@BF12390.ASP.CY09.JAN.H.V0917">MU00.@BF12390.ASP.CY09.JAN.H.V0917</a>	X	X	X	X	X	X		X		
6585.1.16	If released by CMS, contractors shall overlay or manually update the previous January 2009 file with the new January 2009 ASP drug pricing file.	X	X	X	X	X	X		X		
6585.1.17	If released by CMS, contractors shall use the revised January 2009 ASP drug pricing file to determine the payment limit for claims for separately payable Medicare Part B drugs processed or reprocessed on or after October 5, 2009 with dates of service January 1, 2009, through March 31, 2009.	X	X	X	X	X	X		X		
6585.1.18	If released by CMS, contractors shall retrieve the revised January 2009 ASP NOC pricing file from the CMS ASP Web page on or after September 17, 2009.	X	X		X	X					
6585.1.19	If released by CMS, contractors shall use the revised January 2009 ASP NOC pricing file to determine the payment limit for claims for separately payable Medicare Part B drugs processed or reprocessed on or after October 5, 2009 with dates of service January 1, 2009, through March 31, 2009.	X	X		X	X	X		X		
6585.1.20	If released by CMS, contractors shall	X	X	X	X	X	X		X		

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A / B  M A C	D M E  M A C	F I	C A R R I E R	R H H I	Shared-System Maintainers				OTHER
							F I S S	M C S	V M S	C W F	
	download the revised October 2008 ASP drug pricing file through the CDC on or after September 17, 2009. Final File: <a href="mailto:MU00.@BF12390.ASP.CY08.OCT.H.V0917">MU00.@BF12390.ASP.CY08.OCT.H.V0917</a>										
6585.1.21	If released by CMS, contractors shall overlay or manually update the previous October 2008 file with the new October 2008 ASP drug pricing file.	X	X	X	X	X	X		X		
6585.1.22	If released by CMS, contractors shall use the revised October 2008 ASP drug pricing file to determine the payment limit for claims for separately payable Medicare Part B drugs processed or reprocessed on or after October 5, 2009 with dates of service October 1, 2008, through December 31, 2008.	X	X	X	X	X	X		X		
6585.1.23	If released by CMS, contractors shall retrieve the revised October 2008 ASP NOC pricing file from the CMS ASP Web page on or after September 17, 2009.	X	X		X	X					
6585.1.24	If released by CMS, contractors shall use the revised October 2008 ASP NOC pricing file to determine the payment limit for claims for separately payable Medicare Part B drugs processed or reprocessed on or after October 5, 2009 with dates of service October 1, 2008, through December 31, 2008.	X	X		X	X	X		X		
6585.2	Contractors shall not search and adjust claims that have already been processed unless brought to their attention.	X	X	X	X	X	X		X		
6585.3	Notification of successful receipt shall be sent via e-mail to <a href="mailto:price_file_receipt@cms.hhs.gov">price_file_receipt@cms.hhs.gov</a> stating the name of the file received and the entity for which it was received (e.g., carrier/DME MAC/fiscal intermediary name and number).	X	X	X	X	X	X		X		
6585.4	Contractors shall refer to the eChimp bulletin board at <a href="https://echimp.cmsnet/eChimpWeb/login.jsp">https://echimp.cmsnet/eChimpWeb/login.jsp</a>	X	X	X	X	X					

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A / B  M A C	D M E  M A C	F I	C A R R I E R	R H H I	Shared-System Maintainers				OTHER
							F I S S	M C S	V M S	C W F	
	on or after September 17, 2009 for updates on the ASP pricing files actually released. An e-mail from eChimp will be sent to contractors of any updates.										
6585.5	The ASP and NOC drug pricing files will contain the applicable payment allowance limits (i.e., 106% ASP, 106% WAC, or 95% AWP); therefore, Medicare contractors shall not make any additional payment calculations.	X	X	X	X	X	X		X		
6585.6	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, the Medicare Claims Processing Manual, Chapter 17, Section 20.1.3, and JSM-06391.	X	X	X	X	X	X		X		
6585.6.1	FIs should seek payment allowances not on the ASP file from their local carrier for drugs and biologicals.	X		X		X					
6585.7	At the contractor's discretion, contractors should 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.	X	X	X	X	X					
6585.7.1	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		
6585.7.1.1	Contractors shall contact CMS via e-mail at <a href="mailto:sec303aspdata@cms.hhs.gov">sec303aspdata@cms.hhs.gov</a> .	X	X	X	X	X					
6585.7.1.2	Contractors shall include "Pricing Request" in the subject line.	X	X	X	X	X					
6585.7.2	At the contractor's discretion, contractors should contact CMS to request additions or deletions of billing codes, drugs and/or payment limits to the ASP and/or ASP NOC files, including payment limits for DME infused drugs.	X	X	X	X	X					



Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A / B  M A C	D M E  M A C	F I	C A R R I E R	R H I	Shared-System Maintainers				OTHER
							F I S S	M C S	V M S	C W F	
6585.7.2.1	Contractors shall contact CMS via e-mail at <a href="mailto:sec303aspdata@cms.hhs.gov">sec303aspdata@cms.hhs.gov</a> .	X	X	X	X	X					
6585.7.2.2	Contractors shall include "Pricing Request" in the subject line.	X	X	X	X	X					
6585.8	Contractors shall make separate payment for the blood clotting factor furnishing fee when separate payment for the blood clotting factor is allowed and the payment limit for the blood clotting factor is not included on the ASP or NOC file.	X		X	X	X					
6585.8.1	For dates of service January 1, 2006, through December 31, 2006, the blood clotting factor furnishing fee of \$0.146 per I.U. is added to the payment limit for the blood clotting factor.	X		X	X	X					
6585.8.2	For dates of service January 1, 2007, through December 31, 2007, the blood clotting factor furnishing fee of \$0.152 per I.U. is added to the payment limit for the blood clotting factor.	X		X	X	X					
6585.8.3	For dates of service January 1, 2008, through December 31, 2008, the blood clotting factor furnishing fee of \$0.158 per I.U. is added to the payment limit for the blood clotting factor.	X		X	X	X					
6585.8.4	For dates of service January 1, 2009, through December 31, 2009, the blood clotting factor furnishing fee of \$0.164 per I.U. is added to the payment limit for the blood clotting factor.	X		X	X	X					
6585.9	Contractors shall use the most current version available of 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					
6585.9.1	Contractors shall use the template to report	X	X	X	X	X					

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A / B  M A C	D M E  M A C	F I	C A R R I E R	R H I	Shared-System Maintainers				OTHER
							F I S S	M C S	V M S	C W F	
	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.										
6585.9.2	Contractors shall list all drugs that were priced since the last submitted report.	X	X	X	X	X					
6585.9.3	Contractors shall list each drug priced on the report only once.	X	X	X	X	X					
6585.9.4	For compounded drugs, contractors shall report the name of each drug in the compounded product.	X	X	X	X	X					
6585.9.5	Contractors shall prepare and submit the reports so that each report covers approximately 30 days of pricing activity.	X	X	X	X	X					
6585.9.6	Contractors shall report drugs omitted from previous reports in the next report.	X	X	X	X	X					
6585.9.7	Contractors shall complete the report in its entirety.	X	X	X	X	X					
6585.9.8	Contractors do not need to report radiopharmaceuticals.	X			X						
6585.9.9	FIs shall report pricing information for drugs, biologicals, and radiopharmaceuticals that are billed using C9399.	X		X		X					
6585.10	Contractors shall download the most current version available of the template from the CMS Web site at <a href="http://www.cms.hhs.gov/McrPartBDrugAvgSalesPrice/01_overview.asp#TopOfPage">http://www.cms.hhs.gov/McrPartBDrugAvgSalesPrice/01_overview.asp#TopOfPage</a> .	X	X	X	X	X					
6585.11	Contractors shall complete the template on a monthly basis.	X	X	X	X	X					
6585.11.1	The template shall be in MS Excel format.	X	X	X	X	X					
6585.11.2	Contractors shall send the completed template 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					
6585.11.3	If the contractor has not priced any drugs since the last submitted report, in lieu of using the template, the contractor shall send an email to <a href="mailto:Sec303aspdata@cms.hhs.gov">Sec303aspdata@cms.hhs.gov</a> stating that the contractor has no drug pricing to	X	X	X	X	X					

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A / B  M A C	D M E  M A C	F I	C A R R I E R	R H I	Shared-System Maintainers				OTHER
							F I S S	M C S	V M S	C W F	
	report.										

**III. PROVIDER EDUCATION TABLE**

Number	Requirement	Responsibility (place an "X" in each applicable column)								
		A / B  M A C	D M E  M A C	F I	C A R R I E R	R H H I	Shared-System Maintainers			
						F I S S	M C S	V M S	C W F	
6585.12	A provider education article related to this instruction will be available at <a href="http://www.cms.hhs.gov/MLNMattersArticles/">http://www.cms.hhs.gov/MLNMattersArticles/</a> shortly after the CR is released. You will receive notification of the article release via the established "MLN 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 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	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:

**B. For all other recommendations and supporting information, use this space:**

**V. CONTACTS**

**Pre-Implementation Contact(s):** Glenn McGuirk, [Glenn.McGuirk@cms.hhs.gov](mailto:Glenn.McGuirk@cms.hhs.gov)

**Post-Implementation Contact(s):** Bonny Dahm, [Bonny.Dahm@cms.hhs.gov](mailto:Bonny.Dahm@cms.hhs.gov)

## **VI. FUNDING**

**A: *For Fiscal Intermediaries (FIs), Regional Home Health Intermediaries (RHHIs), and/or Carriers:***

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

**B. *For Medicare Administrative Contractors (MAC):***

The Medicare Administrative Contractor (MAC) is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as changes to the MAC Statement of Work (SOW). The contractor is not obligated to incur costs in excess of the amounts specified 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.