CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-04 Medicare Claims Processing	Centers for Medicare & Medicaid Services (CMS)
Transmittal 3354	Date: September 18, 2015
	Change Request 9351

SUBJECT: January 2016 Quarterly Average Sales Price (ASP) Medicare Part B Drug Pricing Files and Revisions to Prior Quarterly Pricing Files

I. SUMMARY OF CHANGES: The ASP methodology is based on quarterly data submitted to CMS by manufacturers. CMS will supply contractors with the ASP and not otherwise classified (NOC) drug pricing files for Medicare Part B drugs on a quarterly basis. Payment allowance limits under the OPPS are incorporated into the Outpatient Code Editor (OCE) through separate instructions that can be located in Chapter 4, section 50 of the IOM.

EFFECTIVE DATE: January 1, 2016

*Unless otherwise specified, the effective date is the date of service. IMPLEMENTATION DATE: January 4, 2016

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:

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

Attachment - Recurring Update Notification

SUBJECT: January 2016 Quarterly Average Sales Price (ASP) Medicare Part B Drug Pricing Files and Revisions to Prior Quarterly Pricing Files

EFFECTIVE DATE: January 1, 2016

*Unless otherwise specified, the effective date is the date of service. IMPLEMENTATION DATE: January 4, 2016

I. GENERAL INFORMATION

A. Background: The ASP methodology is based on quarterly data submitted to CMS by manufacturers. CMS will supply contractors with the ASP and not otherwise classified (NOC) drug pricing files for Medicare Part B drugs on a quarterly basis. Payment allowance limits under the OPPS are incorporated into the Outpatient Code Editor (OCE) through separate instructions that can be located in Chapter 4, section 50 of the IOM.

B. Policy: File: January 2016 ASP and ASP NOC -- Effective Dates of Service: January 1, 2016, through March 31, 2016

File: October 2015 ASP and ASP NOC -- Effective Dates of Service: October 1, 2015, through December 31, 2015

File: July 2015 ASP and ASP NOC -- Effective Dates of Service: July 1, 2015, through September 30, 2015

File: April 2015 ASP and ASP NOC -- Effective Dates of Service: April 1, 2015, through June 30, 2015

File: January 2015 ASP and ASP NOC -- Effective Dates of Service: January 1, 2015, through March 31, 2015

II. BUSINESS REQUIREMENTS TABLE

"Shall" denotes a mandatory requirement, and "should" denotes an optional requirement.

Number	Requirement	Re	espo	nsi	bilit	y				
			A/B MA(D M E		Sys	red- tem aine		Other
		A	В	H H H	M A C	F	M C S		С	
9351.1	The January 2016 and, if released, the revised October 2015, July 2015, April 2015, and January 2015, ASP drug pricing files for Medicare Part B drugs will be available via the CMS Data Center (CDC).									CDC
9351.1.1	Contractors shall download the January 2016 ASP drug pricing file through the CDC on or after December 16, 2015.	X	X	Х	Х					VDC

Number	Requirement Responsibility									
			A/B		D		Sha	red-		Other
			ЛА		M			tem		
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		Α	В	Η		F	M		C	
		11	D	H	Μ		C	M	-	
				H	Α	S	S	S	F	
					С	S	5	5	-	
	Final File:					2				
	MU00.@BF12390.ASP.R2.CY16.JAN.I.V1216.									
9351.1.1. 1	Contractors shall retrieve the January 2016 ASP NOC pricing file from the CMS ASP webpage on or after December 16, 2015.	X	Х	X	X					VDC
9351.1.1.	Contractors shall use the January 2016 ASP and NOC	Χ	Х	Χ	Χ					
2	drug pricing files to determine the payment limit for									
	claims for separately payable Medicare Part B drugs									
	processed or reprocessed on or after January 4, 2016									
	with dates of service January 1, 2016, through March									
	31, 2016.									
9351.1.1.	Contractors shall use the January 2016 ASP drug		Х		Х					
3	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									
	January 4, 2016, with dates of service on or after									
	January 1, 2016.									
9351.1.2	If released by CMS, contractors shall download the	X	Х	X						VDC
9331.1.2	revised October 2015 ASP drug pricing file through	Λ	Λ	Λ						VDC
	the CDC on or after December 16, 2015.									
	Final File:									
	MU00.@BF12390.ASP.R2.CY15.OCT.I.V1216.									
9351.1.2.	If released by CMS, contractors shall overlay or	X	Х	X	X					
1	manually update the previous October 2015 file with	Λ	Λ	Λ	Λ					
1	the new October 2015 ASP drug pricing file.									
9351.1.2.	If released by CMS, contractors shall use the revised	Χ	Х	Х	Х					
2	October 2015 ASP drug pricing file to determine the									
	payment limit for claims for separately payable									
	Medicare Part B drugs processed or reprocessed on or often January 4, 2016 with dates of comise October 1									
	after January 4, 2016 with dates of service October 1, 2015, through December 31, 2015.									
	2015, unougn December 51, 2015.									
9351.1.2.	If released by CMS, contractors shall retrieve the	Χ	Х	Χ	Х					VDC
3	revised October 2015 ASP NOC pricing file from the									
	CMS ASP webpage on or after December 16, 2015.									
9351.1.2.	If released by CMS, contractors shall use the revised	X	Х	X	X					
4	October 2015 ASP NOC pricing file to determine the		Δ	Δ	Δ					
	payment limit for claims for separately payable									
	Medicare Part B drugs processed or reprocessed on or									
	O I TITLE OI OI OI	1	L	I	1		L	1	I	L

Number	Requirement	Re	espo	onsi	bilit	v				
1 (unified			A/B		D		Sha	red-		Other
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				H	Μ		C		-	
				Н	Α	S	S	S	F	
					С	S				
	after January 4, 2016 with dates of service October 1, 2015, through December 31, 2015.									
9351.1.3	If released by CMS, contractors shall download the revised July 2015 ASP drug pricing file through the CDC on or after December 16, 2015.	X	X	X	X					VDC
	Final File: MU00.@BF12390.ASP.R2.CY15.JUL.I.V1216.									
9351.1.3. 1	If released by CMS, contractors shall overlay or manually update the previous July 2015 file with the new July 2015 ASP drug pricing file.	X	X	X	X					
9351.1.3. 2	If released by CMS, contractors shall use the revised July 2015 ASP drug pricing file to determine the payment limit for claims for separately payable Medicare Part B drugs processed or reprocessed on or after January 4, 2016 with dates of service July 1, 2015, through September 30, 2015.	X	X	X	X					
9351.1.3. 3	If released by CMS, contractors shall retrieve the revised July 2015 ASP NOC pricing file from the CMS ASP webpage on or after December 16, 2015.	X	X	X	X					VDC
9351.1.3. 4	If released by CMS, contractors shall use the revised July 2015 ASP NOC pricing file to determine the payment limit for claims for separately payable Medicare Part B drugs processed or reprocessed on or after January 4, 2016 with dates of service July 1, 2015, through September 30, 2015.	X	X	X	X					
9351.1.4	If released by CMS, contractors shall download the revised April 2015 ASP drug pricing file through the CDC on or after December 16, 2015. Final File:	X	X	X	X					VDC
	MU00.@BF12390.ASP.R2.CY15.APR.I.V1216.									
9351.1.4. 1	If released by CMS, contractors shall overlay or manually update the previous April 2015 file with the new April 2015 ASP drug pricing file.	X	X	X	X					
9351.1.4. 2	If released by CMS, contractors shall use the revised April 2015 ASP drug pricing file to determine the payment limit for claims for separately payable Medicare Part B drugs processed or reprocessed on or	X	X	X	X					

Number	Requirement	Re	espo	nsil	bilit	v				
		1	A/B		D	ľ.	Sha	red-		Other
			MA(Μ			tem		
					Е		•	aine		
		Α	В	Η		F	Μ	V	C	
				Н	Μ		С	Μ	W	
				Н	А	S	S	S	F	
					С	S				
	after January 4, 2016 with dates of service April 1,									
	2015, through June 30, 2015.									
9351.1.4. 3	If released by CMS, contractors shall retrieve the revised April 2015 ASP NOC pricing file from the CMS ASP webpage on or after December 16, 2015.	X	X	Х	X					VDC
9351.1.4. 4	If released by CMS, contractors shall use the revised April 2015 ASP NOC pricing file to determine the	X	Χ	X	X					
4	payment limit for claims for separately payable									
	Medicare Part B drugs processed or reprocessed on or									
	after January 4, 2016 with dates of service April 1,									
	2015, through June 30, 2015.									
9351.1.5	If released by CMS, contractors shall download the	Χ	Χ	Х	Х					VDC
	revised January 2015 ASP drug pricing file through									
	the CDC on or after December 16, 2015.									
	Final File:									
	MU00.@BF12390.ASP.R2.CY15.JAN.I.V1216.									
9351.1.5.	If released by CMS, contractors shall overlay or	Х	Χ	Х	Х					
1	manually update the previous January 2015 file with									
	the new January 2015 ASP drug pricing file.									
0251 1 5		37	37	37	37					
9351.1.5.	If released by CMS, contractors shall use the revised	X	Х	Х	Х					
2	January 2015 ASP drug pricing file to determine the payment limit for claims for separately payable									
	Medicare Part B drugs processed or reprocessed on or									
	after January 4, 2016 with dates of service January 1,									
	2015, through March 31, 2015.									
9351.1.5.	If released by CMS, contractors shall retrieve the	Χ	Χ	Х	Х					VDC
3	revised January 2015 ASP NOC pricing file from the									
	CMS ASP webpage on or after December 16, 2015.									
9351.1.5.	If released by CMS, contractors shall use the revised	X	X	X	X					
4	January 2015 ASP NOC pricing file to determine the		Δ	1	1					
	payment limit for claims for separately payable									
	Medicare Part B drugs processed or reprocessed on or									
	after January 4, 2016 with dates of service January 1,									
	2015, through March 31, 2015.									
0051.5		.	.		.					
9351.2	Contractors shall not search and adjust claims that	Х	Χ	Х	Х					
	have already been processed unless brought to their attention.									
		I	I							

Number	Requirement	R	espo	onsi	bilit	v				
			A/B		D	r	Sha	red-		Other
		I	MA	С	Μ		Sys	tem		
					Е		aint			
		Α	В	Η		F	Μ		С	
		11		H	Μ		C	M	-	
				H	Α	S	S	S	F	
					С	Š	~	~	-	
9351.3	Notification of successful receipt shall be sent via e- email to price_file_receipt@cms.hhs.gov stating the name of the file received and the entity for which it	X	X	X	X					VDC
	was received (e.g., carrier/DME MAC/fiscal intermediary name and number).									
9351.4	The ASP and NOC drug pricing files will contain the	X	X	X	X					
	applicable payment allowance limits (i.e., 106% ASP,									
	106% WAC, or 95% AWP); therefore, Medicare									
	contractors shall not make any additional payment calculations.									
9351.5	For any drug or biological not listed in the ASP or	X	X	X	X					
	NOC drug pricing files, contractors shall determine the payment allowance limits in accordance with the									
	policy described in the Medicare Claims Processing Manual, Chapter 17, Section 20.1.3.									
9351.5.1	A/B MAC Part A shall seek payment allowances not	X		X						
,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	on the ASP file from their local carrier for drugs and biologicals.			11						
9351.6	Contractors shall use the most current version	X	X	X	X					
	available of the Medicare Contractor Reporting Template for Part B drugs to report information on Madisare Part B drugs not raid on a cost or									
	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.									
9351.6.1	Contractors shall use the template to report pricing	X	X	X	X					
	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.									
9351.6.2	Contractors shall list all drugs that were priced since	X	X	X	X					
	the last submitted report.									
9351.6.3	Contractors shall list each drug priced on the report only once.	X	X	X	X					
9351.6.4	For compounded drugs, contractors shall report the	X	X	X	X			<u> </u>		
	name of each drug in the compounded product.									
9351.6.5	Contractors shall prepare and submit the reports so that each report covers approximately 30 days of	X	X	X	X					

Number	Requirement Responsibility									
			A/B MA(D M E		Sys	red- tem aine		Other
		A	В	H H H	M A C	F I S S	M C S		C W F	
	pricing activity.									
9351.6.6	Contractors shall report drugs omitted from previous reports in the next report.	X	X	X	X					
9351.6.7	Contractors shall complete the report in its entirety.	X	X	X	X					
9351.6.8	Contractors do not need to report radiopharmaceuticals.		X							
9351.6.9	A/B MAC Part A shall report pricing information for drugs, biologicals, and radiopharmaceuticals that are billed using C9399.	X		X						
9351.6.10	Contractors shall download the most current version available of the template from the CMS Web site at http://www.cms.gov/McrPartBDrugAvgSalesPrice/.	X	X	X	X					
9351.6.11	Contractors shall complete the template on a monthly basis.	X	X	X	Х					
9351.6.12	The template shall be in MS Excel format.	X	X	X	X					
9351.6.13	Contractors shall send the completed template to sec303aspdata@cms.hhs.gov on the first business day of the month.	X	X	X	X					
9351.6.14	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 Sec303aspdata@cms.hhs.gov stating that the contractor has no drug pricing to report.	X	X	X	X					

III. PROVIDER EDUCATION TABLE

Number	Requirement	Re	spoi	nsibi	ility	
			A/B		D	С
		1	MAC		Μ	Е
					Е	D
		Α	В	Η		Ι
				Η	Μ	
				Η	A	
					С	
9351.7	MLN Article: A provider education article related to this instruction will be	Х	Х	Х	Х	

Number	Requirement	Re	spo	nsib	ility	
			A/B MAC		D M E	C E D
		A	В	H H H	M A C	Ι
	available at http://www.cms.gov/Outreach-and-Education/Medicare-Learning- Network-MLN/MLNMattersArticles/ 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 sites and include information about it in a listserv message within 5 business days after receipt of the notification from CMS announcing the availability of the article. In addition, the provider education article shall be included in the contractor's 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.					

IV. SUPPORTING INFORMATION

Section A: Recommendations and supporting information associated with listed requirements: N/A

"Should" denotes a recommendation.

X-Ref	Recommendations or other supporting information:
Requirement	
Number	

Section B: All other recommendations and supporting information: N/A

V. CONTACTS

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

Post-Implementation Contact(s): Contact your Contracting Officer's Representative (COR).

VI. FUNDING

Section A: 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.

ATTACHMENTS: 0