CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-20 One-Time Notification	Centers for Medicare & Medicaid Services (CMS)
Transmittal 457	**Date: MARCH 20, 2009**
	Change Request 6402

SUBJECT: Hemophilia Clotting Factor Indicator on Average Sales Price (ASP) Drug Pricing File

I. SUMMARY OF CHANGES: In order for FIs and Part A MACs to make appropriate payment for the blood clotting factor in an efficient and effective manner, CMS has modified the Average Sales Price (ASP) drug pricing file format to include a field that will identify a HCPCS code as being eligible for the add-on payment. This instruction includes a new ASP drug pricing file format that is intended for FI and Part A-MAC use only.

New / Revised Material
Effective Date: July 1, 2009
Implementation Date: July 6, 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:

One-Time Notification

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

Pub. 100-20	Transmittal: 457	Date: March 20, 2009	Change Request: 6402

SUBJECT: Hemophilia Clotting Factor Indicator on Average Sales Price (ASP) Drug Pricing File

Effective Date: July 1, 2009
Implementation Date: July 6, 2009

I.   GENERAL INFORMATION

A.   Background: Section 1842(o)(5) of the Social Security Act allows for payment of a blood clotting factor add-on fee. In order for FIs and Part A MACs to make appropriate payment for blood clotting factors in an efficient and effective manner, CMS has modified the ASP drug pricing file format to include a field that will identify a HCPCS code as being eligible for the add-on payment. This instruction includes a new ASP drug pricing file format.

B.   Policy: Beginning July 1, 2009, a new "clotting factor" column will be included in future ASP pricing files. In this column, the indicator "1" will identify the nationally priced clotting factors with a unique HCPCS code. Instructions on the intended use of this column are provided in Change Request 6354. Only the FIs and Part A MACs will update the hemophilia indicator with new hemophilia clotting factors using the Part B drug pricing files (ASP) that are issued quarterly by CMS.

II.   BUSINESS REQUIREMENTS TABLE

"Shall" denotes a mandatory requirement

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A / B MAC	D M E MAC	FI	C A R R I E R	R H H I	Shared-System Maintainers				Other
							FISS	MCS	VMS	CWF	
6402.1	A test file will be available via the CMS Data Center (CDC) or after April 14, 2009.										CMS
6402.2	Contractors shall download the test file through the CDC on or after April 14, 2009. The Final File Name is MU00.@BF12390.ASP.R2.CY09.TST0414	X	X	X	X		X				
6402.3	Beginning with the July 2009 ASP drug pricing file, contractors shall use the new file layout.	X	X	X	X	X	X	X			
6402.4	FIs and Part A MACs shall use the new ASP drug pricing file format as described in Change Request 6354.	X		X			X				
6402.5	This new ASP file format is not intended to change any current practices among contractors except for FIs and Part A MACs.	X	X	X	X	X		X			
6402.6	Contractors shall continue to use the previous file layout for revised ASP pricing files for quarters prior to July 2009.	X	X	X	X	X	X	X			

III.   PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A / B MAC	D M E MAC	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	
	None.										

IV.   SUPPORTING INFORMATION

Should" denotes a recommendation.

Section A: Recommendations and supporting information associated with listed requirements

X-Ref Requirement Number	Recommendations or other supporting information:
CR 6354	

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

V. CONTACTS

Pre-Implementation Contact(s):
Policy: Cheryl Gilbreath at Cheryl.Gilbreath@cms.hhs.gov or 410-786-5919
Institutional Claims Processing: Cindy Murphy at Cindy.Murphy@cms.hhs.gov or 410-786-5733

Post-Implementation Contact(s): Appropriate Regional Office

VI. FUNDING

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

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.

ATTACHMENT: Record Layout for the ASP File – 3 Decimal Positions