CMS Manual System Pub. 100-20 One-Time Notification Department of Health & Human Services (DHHS) Centers for Medicare & Medicaid Services (CMS) Transmittal 140 Date: FEBRUARY 3, 2005

CHANGE REQUEST 3728

SUBJECT: Revisions to January 2005 Quarterly Average Sales Price (ASP) Medicare Part B Drug Pricing File

I. SUMMARY OF CHANGES: This One-Time Notification informs Medicare contractors to revise certain Medicare Part B drug payment limits for dates of service on or after January 1, 2005, and on or before March 31, 2005.

NEW/REVISED MATERIAL - EFFECTIVE DATE*: January 1, 2005 IMPLEMENTATION DATE: February 4, 2005

Disclaimer for manual changes only: The revision date and transmittal number apply to the red italicized material only. 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
(R = REVISED, N = NEW, D = DELETED) – (Only One Per Row.)

R/N/D	CHAPTER/SECTION/SUBSECTION/TITLE
	N/A

III. FUNDING: Medicare contractors shall implement these instructions within their current operating budgets.

IV. ATTACHMENTS:

	Business Requirements
	Manual Instruction
	Confidential Requirements
X	One-Time Notification
	Recurring Update Notification

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

Attachment – One-Time Notification

Pub. 100-20	Transmittal: 140	Date: February 3, 2005	Change Request 3728
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SUBJECT: Revisions to January 2005 Quarterly Average Sales Price (ASP) Medicare Part B Drug Pricing File

I. GENERAL INFORMATION

- **A. Background:** Section 303(c) of the MMA revises the payment methodology for Part B covered drugs that are not paid on a cost or prospective payment basis. Per MMA of 2003, beginning January 1, 2005, drugs and biologicals not paid on a cost or prospective payment basis will be paid based on the new Average Sale Price (ASP) methodology. The ASP payment methodology is based on data submitted to CMS by manufacturers at the 11-digit National Drug Code (NDC) level. Manufacturers are to report timely and accurate ASP data to CMS. CMS uses published drug pricing compendia and other sources to identify the number of billable units per NDC. Through receipt of additional information, CMS has determined that certain payment limits included in the first quarter 2005 (1Q05) Medicare Part B Drug Pricing File need revision.
- **B. Policy:** Section 1847A(b) the Social Security Act specifies that the ASP payment methodology is used to determine the payment allowance limits for drugs and biologicals subject to that methodology. Based on additional data, the 1Q05 payment allowance limit for the codes indicated in Table 1 below have been revised. The revised payment limits in Table 1 and Table 2 apply to dates of service on or after January 1, 2005, and on or before March 31, 2005.

Note that the ASP-based 1Q05 payment limit for J7510, Q4054, and Q4055 are now provided. The revised payment limit for 90740, a vaccine, is based on 95% of the average wholesale price (AWP). The revised payment limits for the blood clotting factor codes includes the \$0.14 per I.U. furnishing fee. The payment limits in Table 2 are for certain new drugs. CMS will update the MS Excel files on the CMS Web site (www.cms.hhs.gov/providers/drugs/asp.asp) to reflect the payment limits contained in this notice.

Table 1

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HCPCS	Short Description	HCPCS Code	1Q05	1Q05	1Q05
		Dosage	Payment	Independent	Vaccine
			Limit	ESRD Limit	Limit
90740	Hepb vacc, ill pat 3 dose im	3 DOSE SCH	\$113.91	\$113.91	\$113.91
J7190*	Factor viii	I.U.	\$0.66	\$0.66	
J7191*	Factor viii (porcine)	I.U.	\$1.86	\$1.86	
J7192*	Factor viii recombinant	I.U.	\$1.06	\$1.06	
J7193*	Factor ix non-recombinant	I.U.	\$0.89	\$0.89	
J7194*	Factor ix complex	I.U.	\$0.63	\$0.63	
J7195*	Factor ix recombinant	I.U.	\$0.98	\$0.98	
J7197*	Antithrombin iii injection	I.U.	\$1.72	\$1.72	

HCPCS	Short Description	HCPCS Code	1Q05	1Q05	1Q05
		Dosage	Payment	Independent	Vaccine
			Limit	ESRD Limit	Limit
J7198*	Anti-inhibitor	I.U.	\$1.23	\$1.23	
J7510	Prednisolone oral per 5 mg	5 MG	\$0.05	\$0.05	
Q0187*	Factor viia recombinant	1.2 MG	\$1,051.45	\$1,051.45	
Q2022*	VonWillebrandFactrCmplxperIU	I.U.	\$0.86	\$0.86	
Q4054	Darbepoetin alfa, esrd use	1 MCG	\$3.54	\$3.54	
Q4055	Epoetin alfa, esrd use	1000 UNITS	\$9.32	\$9.76	

^{*}The ASP-based payment allowance limit for blood clotting factors and the furnishing fee for blood clotting factors do not apply to inpatient claims.

Table 2

HCPCS	Drug Name	Dosage	1Q05	1Q05	1Q05
Code			Payment	Independent	Vaccine
			Limit	ESRD Limit	Limit
J3490	Pegaptamib sodium	0.3 MG	\$1,054.70	\$1,054.70	
J9999	Histrelin Implant	5 MG	\$530.00	\$530.00	
J9999	Natalizumab	5 MG	\$31.94	\$31.94	

The revised payment limits in this notification supersede the payment limits for these codes in any publication published prior to this document. Note that the absence or presence of a HCPCS code and its associated payment limit does not indicate Medicare coverage of the drug or biological.

C. Provider Education: A Medlearn Matters provider education article related to this instruction will be available at www.cms.hhs.gov/medlearn/matters 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 one week of the availability of the provider education article. In addition, the provider education article must be included in your next regularly scheduled bulletin. 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.

II. BUSINESS REQUIREMENTS

"Shall" denotes a mandatory requirement

[&]quot;Should" denotes an optional requirement

Requirement Number	Requirements		_			y (" app		indi	cate	es the
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		FI	RHHI	Carrier	DMERC	FISS	MCS	VMS	CWF	
3728.1	Contractors shall use the specific payment limit for the HCPCS drug codes listed in Table 1 under section B of this instruction. Contractors shall use the specific payment limits in Table 2 under section B of this instruction for the listed drugs.	X		X	X					
3728.2	Contractors shall not search and adjust claims that have already been processed unless brought to their attention.	X	X	X	X					

III. 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

IV. SCHEDULE, CONTACTS, AND FUNDING

Effective Date*: January 1, 2005 Implementation Date: February 4, 2005	Medicare contractors shall implement these instructions within their current operating budgets.
Pre-Implementation Contact(s): Marjorie Baldo at 410-786-4617 Catherine Jansto at 410-786-7762	
Post-Implementation Contact(s): Appropriate Regional Office	

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