

<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 2424</b>	<b>Date: March 16, 2012</b>
	<b>Change Request 7741</b>

**SUBJECT: Influenza Virus Vaccine Annual Payment Limit Effective Date**

**I. SUMMARY OF CHANGES:** Influenza Virus Vaccine Annual Payment Limit Effective Date

**EFFECTIVE DATE:** August 1, 2012

**IMPLEMENTATION DATE:** August 1, 2012

*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.

<b>R/N/D</b>	<b>CHAPTER / SECTION / SUBSECTION / TITLE</b>
R	Chapter 17 - Drugs and Biologicals 20.1.3 / Exceptions to Average Sales Price (ASP) Payment Methodology

**III. FUNDING:**

**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.

**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:**

**Business Requirements**

**Manual Instruction**

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

# Attachment - Business Requirements

Pub. 100-04	Transmittal: 2424	Date: March 16, 2012	Change Request: 7741
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**SUBJECT:** Influenza Virus Vaccine Annual Payment Limit Effective Date

**Effective Date:** August 1, 2012

**Implementation Date:** August 1, 2012

## I. GENERAL INFORMATION

**A. Background:** The instructions in this transmittal are revising the Center for Medicare & Medicaid Services' (CMS) current language regarding the annual payment limit effective date for seasonal influenza vaccine administration to better conform to the Center for Disease Control and Prevention's (CDC) recommendations for the prevention and control of influenza. We are changing the payment limit effective date from September 1 to August 1. Recent CDC recommendations state that vaccination efforts should begin as soon as the seasonal influenza vaccine is available and continue through the influenza season ([http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5908a1.htm?s\\_cid=rr5908a1\\_w](http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5908a1.htm?s_cid=rr5908a1_w)). CMS also recognizes that the beginning and duration of influenza season cannot be precisely determined. Consistent with previous instructions, CMS' policy continues to recognize that, typically, one seasonal influenza vaccination is allowable per influenza season and it is not anticipated that significant changes to contractors' procedures will be required to comply with these instructions. With this CR, CMS will also correct a clerical error in paragraph 3 and a typographical error in paragraph 4.

**B. Policy:** Effective for services furnished on or after May 1, 1993, the influenza virus vaccine and its administration are covered when furnished in compliance with any applicable State law. Typically, this vaccine is administered once a year in the fall or winter. Medicare Part B provides 100% coverage for the influenza vaccine and its administration as a preventive service. The Part B deductible and coinsurance do not apply for the influenza vaccine and its administration.

## II. BUSINESS REQUIREMENTS TABLE

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A / B  M A C	D M E  M A C	F I  I E R	C A R I E R	R H H I  S S	Shared-System Maintainers				OTHER
							F I S	M C S	V M S	C W F	
7741.1	Contractors shall note that the instructions included in this transmittal supersede all prior instructions regarding the annual payment limit effective date of seasonal influenza vaccine.	X		X	X	X					

## III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility (place an "X" in each applicable column)
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		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	
	None.										

#### IV. SUPPORTING INFORMATION

**Section A:** For any recommendations and supporting information associated with listed requirements, use the box below: N/A

X-Ref Requirement Number	Recommendations or other supporting information:

**Section B:** For all other recommendations and supporting information, use this space: N/A

#### V. CONTACTS

**Pre-Implementation Contact(s):** Prabath Malluwa-Wadu at (410)786-4620 or [Prabath.malluwa-wadu@cms.hhs.gov](mailto:Prabath.malluwa-wadu@cms.hhs.gov) or Edmund Kasaitis (410) 786-0477 or [Edmund.Kasaitis@cms.hhs.gov](mailto:Edmund.Kasaitis@cms.hhs.gov).

**Post-Implementation Contact(s):** Contact your Contracting Officer's Technical Representative (COTR) or Contractor Manager, as applicable.

#### VI. FUNDING

**Section A:** For *Fiscal Intermediaries (FIs)*, *Regional Home Health Intermediaries (RHHIs)*, and/or *Carriers*, use only one of the following statements:

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.

# Claims Processing Manual

## Chapter 17 - Drugs and Biologicals

### 20.1.3 – Exceptions to Average Sales Price (ASP) Payment Methodology

*(Rev. 2424, Issued: 03-16-12, Effective: 08-01-12; Implementation: 08-01-12)*

The payment allowance limits for blood and blood products (other than blood clotting factors) that are not paid on a reasonable charge or prospective payment basis, 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. Blood and blood products furnished in the hospital outpatient department are paid under OPPTS at the amount specified for the Ambulatory Payment Classification (APC) to which the product is assigned.

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, unless the drug is compounded or the drug is furnished incident to a professional service. 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 unless the drug is compounded or the drug is furnished incident to a professional service.

The payment allowance limits for influenza, Pneumococcal and Hepatitis B vaccines are 95 percent of the AWP as reflected in the published compendia except where the vaccine is furnished in a hospital outpatient department. Where the vaccine is administered in the hospital outpatient department, the vaccine is paid at reasonable cost. CMS will supply contractors with the payment allowance limits annually to be effective on ~~September~~ *August* 1 of each year. Contractors will be notified of the availability of ~~this file~~ *payment allowance limits* via a Recurring Update Notification.

The payment allowance limits for drugs and biologicals 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 (or other application) approved by the Food and Drug Administration, are based on the published Wholesale Acquisition Cost (WAC) or invoice pricing, except under OPPTS where the payment allowance limit is 95 percent of the published AWP. In determining the payment limit based on WAC, the contractors follow the methodology specified in Publication. 100-04, Chapter 17, Drugs and Biologicals, for calculating the AWP, but substitute WAC for AWP. The payment limit is ~~100~~ *106* percent of the lesser of the lowest-priced brand or median generic WAC.

Carriers, DME MACs, and A/B MACs shall develop payment allowance limits for covered drugs when CMS does not supply the payment allowance limit on the ASP drug pricing file. 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.

The payment allowance limits for new drugs and biologicals that are produced or distributed under a new drug application (or other new 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, or invoice pricing if the WAC is not published, except under OPPS where the payment allowance limit is 95 percent of the published AWP. This policy applies only to new drugs that were first sold on or after January 1, 2005. At the contractors discretion, contractors may contact CMS to obtain payment limits for new 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.

The payment allowance limits for radiopharmaceuticals are not subject to ASP. Carriers should determine payment limits for radiopharmaceuticals based on the methodology in place as of November 2003 in the case of radiopharmaceuticals furnished in other than the hospital outpatient department. Refer to Chapter 17, §90.2 of the manual regarding radiopharmaceuticals furnished in the hospital outpatient department.