CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-04 Medicare Claims Processing	Centers for Medicare & Medicaid Services (CMS)
Transmittal 2368	**Date: December 15, 2011**
	Change Request 7397

NOTE: Transmittal 2312 dated September 23, 2011, is being rescinded and replaced with Transmittal 2368, dated December 15, 2011 to change the effective and implementation dates to January 1, 2013. All other material remains the same.

SUBJECT: Pharmacy Billing for Drugs Provided "Incident To" a Physician Service
This CR rescinds and fully replaces CR 7109.

I. SUMMARY OF CHANGES: This Change Request (CR) clarifies policy with respect to restrictions on pharmacy billing for drugs provided incident to a physician service. This CR also clarifies policy for the local determination of payment limits for drugs that are not nationally determined.

EFFECTIVE DATE: January 1, 2013
IMPLEMENTATION DATE: January 1, 2013

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
R	17/10/Payment Rules for Drugs and Biologicals
R	17/20.1.3/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: 2368	Date: December 15, 2011	Change Request: 7397

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SUBJECT: Pharmacy Billing for Drugs Provided "Incident to" a Physician's Service.
(This CR rescinds and fully replaces CR 7109.)

Effective Date: January 1, 2013

Implementation Date: January 1, 2013

I. GENERAL INFORMATION

A. Background:

This Change Request (CR) clarifies policy with respect to restrictions on pharmacy billing for drugs or biologicals furnished "incident to" a physician's service. This CR also clarifies policy for the local determination of payment limits for drugs that are not nationally determined.

B. Policy:

Pharmacies may bill Medicare Part B for certain classes of drugs including: immunosuppressive drugs, oral anti-emetic drugs, oral anti-cancer drugs, and drugs self-administered through any piece of Durable Medicare Equipment. Claims for these drugs are generally submitted to the Durable Medical Equipment Medicare Administrative Contractor (DME MAC). In the rare situation where a pharmacy dispenses a drug that will be administered through implanted DME and a physician's service will not be utilized to fill the pump with the drug, the claim is submitted to the A/B MAC or carrier (See Medicare Claims Processing Manual, Publication 100-04, Chapter 20, section 10). The DME MAC, A/B MAC, or carrier will make payment for these drugs, when deemed to be covered and reasonable and necessary, to the pharmacy. All bills submitted to the DME MAC, A/B MAC, or carrier must be submitted on an assigned basis by the pharmacy. (See Medicare Claims Processing Manual, Publication 100-04, Chapter 17, section 50.B.)

Pharmacies, Suppliers and Providers may not bill Medicare Part B for drugs dispensed directly to a beneficiary for administration "incident to" a physician service, such as refilling an implanted drug pump. These claims must be denied. (See Medicare Claims Processing Manual, Publication 100-04, Chapter 17, section 50.B and Medicare Benefit Policy Manual, Publication 100-02, Chapter 15, sections 50.3.)

Pharmacies may not bill Medicare Part B for drugs furnished to a physician for administration to a Medicare beneficiary. When these drugs are administered in the physician's office to a beneficiary, the only way these drugs can be billed to Medicare is if the physician purchases the drugs from the pharmacy. In this case, the drugs are being administered "incident to" a physician's service and pharmacies may not bill Medicare Part B under the "incident to" provision. (See Medicare Benefit Policy Manual, Publication 100-02, Chapter 15, sections 50.3 and 60.1.)

The payment 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, are based on the published Wholesale Acquisition Cost

(WAC) or invoice pricing, except under OPPS where the payment allowance limit is 95 percent of the published AWP. In determining the payment limit based on WAC, the payment limit is 106 percent of the lesser of the lowest-priced brand or median generic WAC. (See Medicare Claims Processing Manual, Publication 100-04, Chapter 17, section 20.1.3.)

II. BUSINESS REQUIREMENTS TABLE

Use"Shall" to denote a mandatory requirement

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A/B MAC	DME MAC	FI	CARRIER	RHHI	Shared-System Maintainers				OTHER
							FISS	MCS	VMS	CWF	
7397.1	Medicare contractors shall continue to follow the policies as clarified in the Medicare Claims Processing Manual, Publication 100-04, Chapter 17, section 10, when processing claims for Medicare covered drugs.	X	X	X	X	X					
7397.1.1	Medicare contractors shall deny claims from pharmacies for drugs that are furnished "incident to" physician services.	X	X		X						
7397.1.2	Medicare carriers or A/B MACs shall reject claims from pharmacies for self-administered immunosuppressive drugs, self-administered drugs administered through non-implanted durable medical equipment, or self-administered anti-cancer or anti-emetic drugs.	X			X						
7397.1.3	Medicare DME-MACs shall continue to process claims from pharmacies for self-administered immunosuppressive drugs, self-administered drugs administered through non-implanted durable medical equipment, and self-administered anti-cancer or anti-emetic drugs according to current policies.		X								
7397.1.4	Medicare A/B MACs or carriers shall continue to process claims from pharmacies for self-administered drugs administered through implanted durable medical equipment according to current policies.	X			X						
7397.2	Medicare contractors shall continue to follow the policies as clarified in the Medicare Claims Processing Manual, Publication 100-04, Chapter 17, section 20.1.3, when determining local payment limits.	X	X	X	X	X					
7397.3	Medicare contractors shall not search their files to either retract payment for claims already paid or to retroactively pay claims. However, contractors shall adjust claims brought to their attention.	X	X		X						

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A/B MAC	DME MAC	FI	CARRIER	RHHI	Shared-System Maintainers				OTHER
							FISS	MCS	VMS	CWF	
7397.4	A provider education article related to this instruction will be available at http://www.cms.hhs.gov/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 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

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

Use "Should" to denote a recommendation.

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): anne-e-tayloe.hauswald@cms.hhs.gov, 410-786-4546
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:*

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

10 - Payment Rules for Drugs and Biologicals
(Rev.2368, Issued: 12-15-11; Effective: 01-01-13; Implementation: 01-01-13)

Drugs for inpatient hospital and inpatient skilled nursing facility (SNF) beneficiaries are included in the respective prospective payment system (PPS) rates, except for hemophilia clotting factors for hospital inpatients under Part A.

All hospital outpatient drugs are excluded from SDP because the payment allowance for such drugs is determined by a different methodology. Non pass-through drugs with estimated per day costs less than or equal to the applicable drug packaging threshold that are furnished to hospital outpatients are packaged under the outpatient prospective payment system (OPPS). Their costs are recognized and included but paid as part of the ambulatory payment classification (APC) group payment for the service with which they are billed. Non pass-through drugs with estimated per day costs greater than the applicable drug packaging threshold are paid separately.

Drugs that are granted “pass through” payment status are required by law to be paid at either the amount paid under the physician fee schedule, or, if the drug is included in the Part B drug competitive acquisition program (CAP), at the Part B drug CAP rate. Drugs that have pass-through status may have coinsurance amounts that are less than 20 percent of the OPPS payment amount. This is because pass-through payment amounts, by law, are not subject to coinsurance. CMS considers the amount of the pass-through drug payment rate that exceeds the otherwise applicable OPPS payment rate to be the pass-through payment amount. Thus, in situations where the pass-through payment rate exceeds the otherwise applicable OPPS payment rate, the coinsurance is based on a portion of the total drug payment rate, not the full payment rate.

Hospitals must report all appropriate HCPCS codes and charges for separately payable drugs, in addition to reporting the applicable drug administration codes. Hospitals should also report the HCPCS codes and charges for drugs that are packaged into payments for the corresponding drug administration or other separately payable services. Historical hospital cost data may assist with future payment packaging decisions for such drugs. Drugs are billed in multiples of the dosage specified in the HCPCS code long descriptor. If the drug dose used in the care of a patient is not a multiple of the HCPCS code dosage descriptor, the provider rounds to the next highest unit based on the HCPCS long descriptor for the code in order to report the dose provided.

If the full dosage provided is less than the dosage for the HCPCS code descriptor specifying the minimum dosage for the drug, the provider reports one unit of the HCPCS code for the minimum dosage amount.

OPPS Pricer includes a table of drugs and prices and provides the contractor with the appropriate prices.

Section 90 relates specifically to billing for hospital outpatients. The remainder of this chapter relates to procedures for pricing and paying DME recipients, and to beneficiaries

who receive drugs under special benefits such as pneumococcal, flu and hepatitis vaccines; clotting factors, immunosuppressive therapy, self administered cancer and anti emetic drugs, and drugs incident to physicians‟ services.

The Medicare Prescription Drug, Improvement, and Modernization Act (MMA) of 2003 defines a Specified Covered Outpatient Drug (SCOD) as a covered outpatient drug for which a separate APC has been established and that is either a radiopharmaceutical agent, or a drug or biological for which payment was made on a pass-through basis on or before December 31, 2002. Payment for SCODs is set, by law, at the average acquisition cost. Under the OPPS, a single payment is made for SCODs that represents payment for both the acquisition cost of the drug and any associated pharmacy overhead or nuclear medicine handling costs.

Drugs or biologicals must meet the coverage requirements in Chapter 15 of the Medicare Benefit Policy Manual. Additionally, for end stage renal disease (ESRD) patients, see the Medicare Benefit Policy Manual, Chapter 11. For ESRD patient billing for drugs and claims processing, see Chapter 8 of this manual.

The following chart describes the *general* payment provisions for drugs.

Table - Drug Payment Methodology

Key to the following Table:
NOTE*S*:
DME MACs do not process claims for blood clotting factors.
Unless noted otherwise, claims for these drugs are submitted to the local MAC
† - Drugs & biologicals outside the composite rate *and/or ESRD PPS* are paid as described in 2 below. Those inside the composite rate *and/or ESRD PPS* are paid as described in 1. *(ESRD PPS effective January 1, 2011)*
1 - Included in PPS rate, or other provider-type all inclusive encounter rate
2 - Price taken from CMS drug/biological pricing file effective on the specific date of service
3 - *Based on* reasonable cost *(101% reasonable cost in CAH)*
4 - Lower of cost or 95% AWP paid for drug in addition to PPS rate, or in addition to reasonable cost if excluded from PPS
5 - OPPS-APC, whether pass-thru drug or not
6 - *Cannot* furnish as that "provider" type
7 - May not bill DME-MAC or MAC for drugs furnished incident-to a physicians' service
8 - Payment made at the time of cost settlement
A - Bills are submitted to the DME MAC
++ Except in the State of Washington, where CMS permits the *ESRD Facility* to bill *for* immunosuppressive *drugs* due to the unique State assistance to the beneficiary provided only via the *ESRD Facility*.

Provider/Drug	**Hepatitis B Vaccine**	**Pneumococcal & *Influenza* Vaccines**	**Hemophilia Clotting Factors**	**Immuno - Suppressive**	***Erythropoiesis Stimulating Agents (ESA's)***	**Self Admin Anti-Cancer Anti-Emetic *for cancer treatment***	**Other Drugs**
Hospital Inpatient (IP) A -Prospective Payment System (IPPS)	*3*	*3*	*2*	1	1	1	1
Hospital IP A - not IPPS	3	3	3	3	3	3	3
Hospital Outpatient Prospective Payment System (OPPS)	*3*	3	*3*	5 *(30 day supply)*	5	5	5
Skilled Nursing Facility (SNF) IP	*3*	*3*	1	1	1	1	1
SNF *OP or* IP B	3	3	3	3	6	6	6
End Stage Renal Disease (ESRD) Facility	*2*	*2*	6	6++	*1 or 2†*	6	*1 or 2†*
Comprehensive Outpatient Rehabilitation Facility (CORF)/ Outpatient Rehabilitation Facility (ORF)	*2*	*2*	6	*6*	*6*	6	*6*
Community Mental Health *Center* (CMHC)	6	6	6	6	6	6	6
Rural Health Clinical (RHC)/Federally	*1*	*8*	5	5	5	5	5

Qualified Health Clinic (FQHC) -hospital based							
RHC/FQHC-independent	*1*	*8*	*6*	*6*	*6*	*6*	*6*
Home Health Agencies (HHA)	*3*	3	*6*	*6*	*6*	*6*	*6 (except for osteoporosis)*
Hospice	6	6	6	6	1	1	1
Physicians	2	2	2	2	2	2	2
Pharmacy	2	2	2 *,7*	2, *A*	*2*	2, *A*	2 *,7*
Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Supplier	2	2	2	2	*2*	2	2
Critical Access Hospital (CAH) *IP or OP* Method I *or II*	3	3	3	3	3	3	3

NOTE*S*:

Independent and provider-based RHCs *and FQHCs generally* do not bill for *pneumococcal/influenza* vaccines*, except when the only service involved is the administration of the vaccine. Instead, RHCs/FQHCs are generally paid for pneumococcal/influenza vaccines at cost settlement via the Medicare cost report. Hepatitis B vaccine payment is* bundled into the encounter rate *for both Independent and provider-based RHCs and FQHCs.*

Influenza, pneumococcal, and Hepatitis B vaccine*s are* paid on a reasonable cost basis in a hospital outpatient department. *Neither* deductible *nor* coinsurance apply.

HHAs cannot bill for vaccines, except on TOB 34X, since vaccines are not part of the HH benefit and cannot be paid under HH PPS.

Influenza, PPV, and Hepatitis B vaccines are paid once for the vaccine and once for the administration of the vaccine. The provider or supplier (including physician) must enter each of the HCPCS on separate lines of the claim.

A Part B blood clotting factor claim from a Part B supplier is processed by the Local Part B Carrier.

A Part A blood clotting factor claim from a Part A provider, including a hospital-based hemophilia center, is processed by the hospital's Medicare contractor.

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

(Rev.2368, Issued: 12-15-11; Effective: 01-01-13; Implementation: 01-01-13)

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 OPPS 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 1 of each year. Contractors will be notified of the availability of this file 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 OPPS 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 *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.