CMS Manual System	**Department of Health & Human Services (DHHS)**
Pub 100-04 Medicare Claims Processing	**Centers for Medicare & Medicaid Services (CMS)**
Transmittal 1698	**Date: MARCH 13, 2009**
	Change Request 6424

SUBJECT: April 2009 Update to the ASC Payment System; Summary of Payment Policy Changes/Manual Revisions.

I. SUMMARY OF CHANGES: In this Change Request, we are issuing instructions to contractors to modify their systems to accept the April 2009 ASC Payment Indicator (PI) file in addition to the updated ASC Drug file, and to ensure that the updated files properly interface with the ASCFS and all other ASC module programming. The April 2009 ASC PI file is a full replacement of the January ASC PI file, and the April 2009 ASC Drug file includes payment rates for all separately payable drugs and biologicals.

This instruction includes updates to Pub. 100-02, chapter 15, section 260.1 and Pub 100-04, chapter 14, section 10.1. The revised language clarifies CMS policy related to potential changes in Medicare certification status by ASCs that are operated by hospitals.

NEW / REVISED MATERIAL
**EFFECTIVE DATE: ***April 1, 2009
IMPLEMENTATION DATE: April 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
R	14/10/10.1/Definition of Ambulatory Surgical Center (ASC)

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:

Manual Instruction
Recurring Update Notification

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

Attachment – Recurring Update Notification

Pub. 100-04	Transmittal: 1698	Date: March 13, 2009	Change Request: 6424

SUBJECT: April 2009 Update to the ASC Payment System; Summary of Payment Policy Changes/Manual Revisions

EFFECTIVE DATE: April 1, 2009

IMPLEMENTATION DATE: April 6, 2009

I. GENERAL INFORMATION

A. Background:

This Recurring Update Notification describes changes to, and billing instructions for, payment policies implemented in the April 2009 ASC payment system update. Final policy under the revised ASC payment system, as set forth in the final rule, Medicare Program; Revised Payment System Policies for Services Furnished in Ambulatory Surgical Centers (ASCs) Beginning in CY 2008, (72 FR 42470), requires that ASC payment rates for covered separately payable drugs and biologicals be consistent with the payment rates under the Medicare hospital outpatient prospective payment system (OPPS). Those rates are updated quarterly. Therefore, beginning with Transmittal 1488, CR 5994 issued April 9, 2008, CMS has issued quarterly updates to ASC payment rates for separately paid drugs and biologicals. CMS also updates the lists of covered surgical procedures and covered ancillary services to include newly created HCPCS codes, as appropriate. This instruction provides an updated payment rate for a current HCPCS drug code, a payment rate and descriptor for a newly created HCPCS drug code and a corrected payment rate for another HCPCS drug code.

The policies related to the CMS updates to the ASC payment system are included in the 2008 ASC payment system instructions: Transmittal 1325, CR 5680, issued August 29, 2007, Transmittal 1415, CR 5885, issued January 18, 2008 and Transmittal 1616, CR6184, issued October 17, 2008.

In this Change Request, we are issuing instructions to contractors to modify their systems to accept the April 2009 ASC PI file in addition to the updated ASC Drug file and to ensure that the updated files properly interface with the ASCFS and all other ASC module programming. The April 2009 ASC PI file is a full replacement of the January ASC PI file and the April 2009 ASC Drug file includes payment rates for all separately payable drugs and biologicals.

This instruction includes updates to Pub. 100-02, chapter 15, section 260.1 and Pub 100-04, chapter 14, section 10.1. The revised language clarifies CMS policy related to potential changes in Medicare certification status by ASCs that are operated by hospitals.

B. Policy:

1. Billing for Drugs and Biologicals

ASCs are strongly encouraged to report charges for all separately payable drugs and biologicals, using the correct HCPCS codes for the items used. ASCs billing for these products must make certain that the reported units of service for the reported HCPCS codes are consistent with the quantity of the drug or biological that was used in the care of the patient. ASCs should not report

HCPCS codes and separate charges for drugs and biologicals that receive packaged payment through the payment for the associated covered surgical procedure.

We remind ASCs that under the ASC payment system if two or more drugs or biologicals are mixed together to facilitate administration, the correct HCPCS codes should be reported separately for each product used in the care of the patient. The mixing together of two or more products does not constitute a "new" drug as regulated by the Food and Drug Administration (FDA) under the New Drug Application (NDA) process. In these situations, ASCs are reminded that it is not appropriate to bill HCPCS code C9399. HCPCS code C9399, Unclassified drug or biological, is for new drugs and biologicals that are approved by the FDA on or after January 1, 2004, for which a HCPCS code has not been assigned.

Unless otherwise specified in the long description, HCPCS descriptions refer to the non-compounded, FDA-approved final product. If a product is compounded and a specific HCPCS code does not exist for the compounded product, the ASC should include the charge for the compounded product in the charge for the surgical procedure performed.

a. New HCPCS Drug and Biological Codes that are Separately Payable under the ASC Payment System as of April 1, 2009

One new HCPCS drug code has been created that is payable for dates of service on or after April 1, 2009. The new HCPCS code, the long descriptor, and payment indicator (PI) are identified in Table 1 below.

Table 1- New Drugs and Biologicals Separately Payable under the ASC Payment System Effective April 1, 2009.

HCPCS	Long Descriptor	P I
C9249	Injection, certolizumab pegol, 1 mg	K2

b. Newly Payable ASC Payment Rate for Certain HCPCS Code Effective January 1, 2009

In the OPPS/ASC final rule with comment period for CY 2009, CMS incorrectly identified HCPCS code J3300 as a drug for which payment would be made as part of the packaged payment for a covered surgical procedure. In fact, HCPCS code J3300 is eligible for separate payment under the revised ASC payment system when it is provided as integral to a covered surgical procedure. Subsequently, CMS issued a correction to the OPPS/ASC final rule with comment period in the January 26, 2009 **Federal Register.** Included in that notice are corrections to the ASC PI and payment rate for HCPCS code J3300 (Injection, triamcinolone acetonide, preservative free, 1 mg) effective January 1, 2009. HCPCS code J3300, the short descriptor, and the corrected PI are displayed in Table 2 below.

Contractors shall ensure that ASCs are aware of this retroactive change and shall notify them that, when appropriate, ASCs may submit claim(s) to receive separate payment for this HCPCS code when the service was originally provided as a packaged service to the surgical procedure during the affected dates of service.

Table 2 – Newly Payable ASC Payment Rate for Certain HCPCS Code Effective January 1, 2009

HCPCS	Short Descriptor	PI	Payment Rate

J3300	Triamcinolone A inj PRS-free	K2	$3.18

c. ASC Payment Rate for Certain Newly Payable HCPCS Code Effective April 1, 2009

For dates of service beginning April 1, 2009, HCPCS code C9247 (Injection, iobenguane, I-123, diagnostic) is eligible for separate payment under the ASC payment system when it is provided integral to a covered surgical procedure. HCPCS code C9247, the short descriptor and the updated PI are displayed in Table 3 below.

Table 3- ASC Payment Rate for Certain Newly Payable HCPCS Code Effective April 1, 2009

HCPCS	Short Descriptor	PI
C9247	Inj, iobenguane, I-123, dx	K2

d. Correct Reporting of Drugs and Biologicals When Used As Implantable Devices

With the exception of drugs and biologicals with pass-through status under the OPPS, ASCs are not to bill separately for drug and biological HCPCS codes when using these items as implantable devices (including as a scaffold or an alternative to human or nonhuman connective tissue or mesh used in a graft) during surgical procedures. As under the OPPS, ASCs are provided a packaged payment for surgical procedures that includes the cost of supportive items, including implantable devices without pass-through status. When using drugs and biologicals during covered surgical procedures as implantable devices, ASCs may include the charges for these items in their charge for the procedure.

e. Correct Reporting of Units for Drugs

ASCs are reminded to ensure that units of drugs administered to patients are accurately reported in terms of the dosage specified in the full HCPCS code descriptor. That is, units should be reported in multiples of the units included in the HCPCS descriptor. For example, if the drug's HCPCS code descriptor specifies 6 mg, and 6 mg of the drug were administered to the patient, the units billed should be 1. As another example, if the drug's HCPCS code descriptor specifies 50 mg, but 200 mg of the drug were administered to the patient, the units billed should be 4. ASCs should not bill the units based on how the drug is packaged, stored, or stocked. That is, if the HCPCS descriptor for the drug code specifies 1 mg and a 10 mg vial of the drug was administered to the patient, 10 units should be reported on the bill, even though only 1 vial was administered. The HCPCS short descriptors are limited to 28 characters, including spaces, so short descriptors do not always capture the complete description of the drug. Therefore, before submitting Medicare claims for drugs and biologicals, it is extremely important to review the complete long descriptors for the applicable HCPCS codes.

2. Payment for Brachytherapy Sources

The Medicare Improvement for Patients and Providers Act of 2008 extended the requirement for CMS to pay hospitals for brachytherapy sources for the period of July 1, 2008 through December 31, 2009, at the hospital's charges adjusted to costs. ASC payment policy is to make payment at the OPPS rate for brachytherapy sources when a prospective rate is available. Consistent with the legislation, there is no prospective rate under the OPPS for the period July 1, 2008 through December 31. 2009. Therefore, for those dates of service payment to ASCs for brachytherapy sources will be made at contractor-priced amounts, consistent with ASC payment policy when no OPPS prospective rate is available.

II. BUSINESS REQUIREMENTS 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	
6424.1	Medicare contractors shall download and install the April 2009 ASC DRUG file FILENAME: MU00.@BF12390.ASC.CY09.DRUG.APR.F.V0320 **Date of retrieval will be provided in a separate email communication from CMS**	X			X			X			
6424.2	Medicare contractors shall download and install a revised January 2009 ASC DRUG file FILENAME: MU00.@BF12390.ASC.CY09.DRUG.JAN.F.V0320 **Date of retrieval will be provided in a separate email communication from CMS**	X			X			X			
6424.3	Medicare contractors shall download and install the April 2009 ASC PI file FILENAME: MU00.@BF12390.ASC.CY09.IND.V0320 **Date of retrieval will be provided in a separate email communication from CMS**	X			X			X			
6424.4	Contractors shall assign TOS F to HCPCS code C9247 and C9249 for claims with DOS on or after April 1, 2009.	X			X					X	
6424.5	Contractors shall assign TOS F to HCPCS code J3300 for claims with DOS on or after January 1, 2009.	X			X					X	
6424.6	Contractors shall allow separate ASC payment, as appropriate, for HCPCS code J3300 for claims with DOS on or after January 1, 2009.	X			X						

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	
6424.7	Contractors shall adjust, as appropriate, claims for HCPCS code J3300 brought to their attention that have dates of service on or after January 1, 2009 but prior to April, 1, 2009.	X			X						
6424.8	Contractors shall allow separate ASC payment, as appropriate, for HCPCS code C9247 for claims with DOS on or after April 1, 2009.	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	
6424.9	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						

IV. SUPPORTING INFORMATION

Section A: For any recommendations and supporting information associated with listed requirements, use the box below:
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: V. CONTACTS

Pre-Implementation Contact(s): ASC Payment Policy: Chuck Braver at chuck.braver@cms.hhs.gov or 410-786-6719; Carrier/ AB MAC Claims Processing Issues: Yvette Cousar at yvette.cousar@cms.hhs.gov or 410-786-2160.
Post-Implementation Contact(s): Regional Office

VI. FUNDING

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

10.1 - Definition of Ambulatory Surgical Center (ASC)

(Rev. 1698; Issued: 03-13-09; Effective Date: 04-01-09; Implementation Date: 04-06-09)

An ASC for Medicare purposes is a distinct entity that operates exclusively for the purpose of furnishing outpatient surgical services to patients. The ASC must enter into a "participating provider" agreement with CMS. An ASC is either independent (i.e., not a part of a provider of services or any other facility), or operated by a hospital (i.e., under the common ownership, licensure or control of a hospital). If an ASC is the latter type, it has the option either of being covered under Medicare as an ASC, or of continuing to be covered as a hospital outpatient surgery department. To be covered as an ASC operated by a hospital, a facility:

- Elects to do so, and continues to be so covered unless CMS determines there is good cause to do otherwise. *This provision is intended to prohibit such an entity from switching from one payment method to another to maximize revenues (47 FR 34082, 34099, Aug. 5, 1982)*;

- Is a separately identifiable entity, physically, administratively, and financially independent and distinct from other operations of the hospital with costs for the ASC treated as a non-reimbursable cost center on the hospital's cost report;

- Meets all the requirements with regard to health and safety, and agrees to the assignment, coverage and payment rules applied to independent ASCs; and

- Is surveyed and approved as complying with the conditions for coverage for ASCs in *42 CFR 416.25-49*.

Related survey requirements are published in the State Operations Manual*, Pub. 100-07, Appendix L*.

If a facility meets the above requirements, it bills *the Medicare contractor* on Form CMS-1500 or the related electronic data set and is paid the ASC payment amount.

If a hospital *operated* facility decides not to become a certified ASC it bills the *Medicare contractor* on Form CMS-1450 or the related EDI data set and is subject to hospital outpatient billing and payment rules. *See chapter 4 for more information.* It is also subject to hospital outpatient certification and participation requirements. *See 42 CFR Part 482 for more information on conditions of participation for hospitals. See Pub 100-07, State Operations Manual, Appendix A, "Survey Protocol, Regulations and Interpretive Guidelines for Hospitals," for information on survey requirements.*

Certain *Indian Health Service (*IHS) and Tribal *hospital outpatient departments* may elect to enroll and be paid as ASCs. See Pub. 100-04, chapter 19 for more information.