CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-08 Medicare Program Integrity	Centers for Medicare & Medicaid Services (CMS)
Transmittal 326	Date: March 12, 2010
	Change Request 6627

SUBJECT: Revision of the Internet Only Manual (IOM) to Remove References to "Purchased Diagnostic Test" and Replace With Language Consistent With the Anti-Markup Rule

I. SUMMARY OF CHANGES: Updates references in the Internet Only Manual (IOM) to "purchased diagnostic tests;" replacing them with the new anti-markup language as finalized by the 2009 PFS final rule (73 FR 69799, November 19, 2008).

EFFECTIVE DATE: June 14, 2010
IMPLEMENTATION DATE: June 14, 2010

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

R/N/D	CHAPTER / SECTION / SUBSECTION / TITLE
R	10/4.19.3/Interpreting Physicians
R	14/14.5/NPIs for Secondary Providers

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

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I. GENERAL INFORMATION to include situations where the TC is not performed in the "office of the billing physician or other supplier." CMS also imposed an anti-markup payment limitation on the professional component (PC) of a diagnostic test ordered by a billing physician or other supplier if the PC is acquired by contractual arrangement or if the PC is not performed in the "office of the billing physician or other supplier." However, in a subsequent final rule (73 FR 405, January 3, 2008), CMS delayed implementation of these new anti-markup provisions with the exception of certain provisions (see 42 CFR §411.351).

Pub. 100-20, Transmittal 445, Change Request 6371, dated February 13, 2009, established claims processing instructions for diagnostic tests subject to the anti-markup payment limitation and the conditions under which the anti-markup provision applies. Transmittal 445, also indicated that the IOM would be updated at a later date to reflect the new anti-markup language.

The CY 2009 final rule (73 FR 69799, November 19, 2008) includes alternative methods for determining when the anti-markup payment limitation

A. Background: Section 1842(n)(1) of the Social Security Act limits payment for certain diagnostic tests where the physician performing or supervising the test does not share a practice with the billing physician or other supplier. Such a test was formerly referred to as a "purchased diagnostic test". This statutory provision was codified in 42 CFR §414.50. Prior to January 1, 2008, 42 CFR §414.50 imposed an "anti-markup" payment limitation to the technical component (TC) of a diagnostic test (other than a clinical diagnostic laboratory test payable under the clinical laboratory fee schedule) that was billed by a physician or other supplier who purchase the test from an outside supplier.

In the CY 2008 Physician Fee Schedule (PFS) final rule (72 FR 66222, November 27, 2007), CMS amended the anti-markup provision in 42 CFR §414.50 to expand the coverage of the anti-markup payment limitation applies. Because this new application of the anti-markup rule is more complex than a simple contractual arrangement between two parties for a TC service, CMS is changing references to the term "purchased diagnostic test" in the IOM) to reflect the new anti-markup language. CMS is not changing all of the references in the manual at one time, but will implement the changes over time beginning with this transmittal. To that end, changes to Pub. 100-04, Claims Processing Manual, chapter 1, §§30.2.9 - 30.2.9.1 and chapter 1, §80.3.2.1.2 will be manualized under separate transmittals. Until all changes are manualized, contractors shall read any reference of "purchased diagnostic test" as "anti-markup test".

B. Policy: This transmittal updates the IOM to conform to the language of the revised regulation 42 CFR §414.50 and directs contractors to take note of the change in nomenclature. Contractors shall consider the term "purchased diagnostic test" to be obsolete. Contractors shall instead use the nomenclature associated with the new anti-markup rule and shall implement the use of the revised language in accordance with the instructions implemented by Transmittal 445 and as reflected in the manual changes presented herein.

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	
6627.1	Contractors shall refer to the updated manuals in the IOM which have been updated to reflect the new anti-markup language.	X			X						
6627.1.1	Contractors shall take note of the manual changes presented in Pub. 100-04, chapter 1, §§10.1.1, 10.1.1.2, 30.2.1, 30.2.2, 30.2.14, and 30.3.7.	X			X						
6627.1.2	Contractors shall take note of the manual changes presented in Pub. 100-04, chapter 12, §20.4.	X			X						
6627.1.3	Contractors shall take note of the manual changes presented in Pub. 100-04, chapter 13, §§20.3, 20.3.1, and 20.3.2.	X			X						
6627.1.4	Contractors shall take note of the manual changes presented in Pub. 100-04, chapter 18, §§20.3 and 20.5.	X			X						
6627.1.5	Contractors shall take note of the manual changes presented in Pub. 100-04, chapter 26, §10.4.	X			X						
6627.1.6	Contractors shall take note of the manual changes presented in Pub. 100-04, chapter 35, §§10.2 and 30.	X			X						
6627.1.7	Contractors shall take note of the manual changes presented in Pub. 100-08, chapter 10, §4.19.3.	X			X						
6627.1.8	Contractors shall take note of the manual changes presented in Pub. 100-08, chapter 14, §14.5.	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	
6627.2	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	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	
	MLN Matters articles with localized information that would benefit their provider community in billing and administering the Medicare program correctly.										

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:
6627.3	Until all changes are manualized, contractors should read any references to "purchased diagnostic tests" as "anti-markup test."
6627.4	Transmittal 445, CR 6371, dated February 13, 2009.

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

V. CONTACTS

Pre-Implementation Contact(s): Felicia Rowe, felicia.rowe@cms.hhs.gov or by phone at (410) 786-5655.

Post-Implementation Contact(s): For issues related to claims processing, contact Felicia Rowe at felicia.rowe@cms.hhs.gov or by phone at (410) 786-5655. For issues related to the anti-markup payment limitation, contact Dave Walczak at david.walczak@cms.hhs.gov or by phone at (410)786-4475.

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),* include the following statement:

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.

4.19.3 – Interpreting Physicians

(Rev.326, Issued: 03-12-10, Effective: 06-14-10, Implementation: 06-14-10)

The applicant shall list all physicians for whose diagnostic test interpretations it will bill. This includes physicians who *will provide interpretations subject to the anti-markup payment limitation as detailed in Pub. 100-04, chapter 1, §30.2.9; whether the service is provided to the IDTF on a contract basis or is reassigned.*

The carrier shall ensure and document that:

- All listed physicians are enrolled in Medicare.

- All interpreting physicians who are reassigning their benefits to the IDTF have the right to do so.

- All required CMS-855R forms have been submitted.

- The interpreting physicians listed are qualified to interpret the types of tests (codes) listed. (The carrier may need to contact another carrier to obtain this information.) If the applicant does not list any interpreting physicians, the carrier need not request additional information because the applicant may not be billing for the interpretations; that is, the physicians may be billing for the interpretation themselves.

If an interpreting physician has been recently added or changed, the new interpreting physician must have met all of the interpreting physician requirements at the time any tests were performed.

14.5 – NPIs for Secondary Providers

(Rev.326, Issued: 03-12-10, Effective: 06-14-10, Implementation: 06-14-10)

When a provider identifier is reported on a paper or electronically submitted Medicare claim to identify an ordering/referring /attending/operating/supervising/*anti-markup* service/other/service facility provider (in the x12N 837 claims transactions) or prescriber (in the NCPDP 5.1 retail drug claim transaction), that identifier must be an NPI. For Medicare purposes, this requirement is effective for claims received on and after May 23, 2008. If the entity to be identified as the ordering/referring/attending/operating/supervising/*anti-markup* service/other/service facility provider or prescriber does not furnish an NPI at the time of the order/referral/*acquisition* or time of service, the billing provider must attempt to obtain that NPI in order to use it in the claim. The billing provider may use the NPI Registry or may need to contact the ordering/referring/ attending/operating/supervising/*anti-markup* service/other/service facility or prescriber in order to obtain the NPI. While the Implementation Guides for the X12N claims transactions permit the reporting of the Social Security Number (SSN) for some secondary providers if there is no NPI, we do not believe the billing provider will be successful in the obtaining the SSN.

- If unable to obtain the NPI of the entity to be identified in the service facility location loop (in the X12 N 837 transaction), no identifier should be reported in that loop.

- If unable to obtain the NPI of the ordering/referring/attending/operating/supervising/*anti-markup* service/other *provider* or prescriber, the billing provider (in the X12N 837 transactions) or the service provider (in the NCPDP 5.1 transactions) shall use its own NPI to identify those secondary providers. Medicare will not pay these claims if these secondary providers are not identified by NPIs.

Effective May 23, 2008, the NPI will replace the UPIN as the unique identifier for all physicians, as defined in 1861 (r) of the Social Security Act, as well as nurse practitioners, clinical nurse specialists, physician assistants, licensed clinical social workers, clinical psychologists, and certified nurse midwives. The only types of providers eligible to refer/order services or items for Medicare beneficiaries are physicians and the non-physician practitioners mentioned above.