| CMS Manual System | **Department of Health & Human Services (DHHS)** |
|---|---|
| Pub 100-20 One-Time Notification | **Centers for Medicare & Medicaid Services (CMS)** |
| **Transmittal 445** | **Date: FEBRUARY 13, 2009** |
| | **Change Request 6371** |

**SUBJECT: Claims Processing Instructions for Diagnostic Tests Subject to the Anti-Markup Pricing Limitation**

**I. SUMMARY OF CHANGES:** In the Calendar Year 2009 Physician Fee Schedule final rule, CMS finalized changes to 42 CFR §414.50 to include alternative methods to determine when not to apply anti-markup payment limitation rules. The intent of this CR is to provide claims processing instructions to contractors when claims with services subject to the anti-markup payment limitation are submitted.

**New / Revised Material**
**Effective Date: July 1, 2009**
**Implementation Date: July 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 |
|---|---|
| N/A | |

**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:**

**One-Time Notification**

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

# Attachment – One-Time Notification

| Pub. 100-20 | Transmittal: 445 | Date: February 13, 2009 | Change Request: 6371 |
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**SUBJECT: Claims Processing Instructions for Diagnostic Tests Subject to the Anti-Markup Pricing Limitation**

**Effective Date**: July 1, 2009

**Implementation Date:** July 6, 2009

## I. GENERAL INFORMATION

**A. Background:** Section 1842(n)(1) of the Social Security Act requires CMS to impose a payment limitation on 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. This rule requires an "anti-markup" payment limitation for the technical component (TC) of a diagnostic test (other than a clinical diagnostic laboratory test payable under the Clinical Laboratory Fee Schedule) that is acquired by contractual arrangement from an outside supplier.

In the CY 2008 PFS final rule (72 FR 66222, November 27, 2007) CMS amended the anti-markup provision in 42 CFR § 414.50. This amendment expands the coverage of the anti-markup payment limitation to include a situation when the TC is not performed in the "office of the billing physician or other supplier." In addition, CMS 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 the implementation of these new anti-markup provisions in 72 FR 66222.

In the CY 2009 PFS final rule (73 FR 69799, November 19, 2008), CMS finalized changes to 42 CFR § 414.50 to include alternative methods to determine when not to apply anti-markup rules. Because this new application of the anti-markup rules is more complex than a simple contractual arrangement between two parties for a TC service, CMS is changing the references of the term "purchased diagnostic test" in the Internet Only Manual to "anti-markup test(s)". CMS will not change all of the references in the manual at this time, but will implement the changes over time. Until that is accomplished, you should read any reference of "purchased diagnostic test" as "anti-markup test". The provision of Publication 100-04, Chapter 16, §40.2 still applies, thus this new anti-markup provision does not apply to independent laboratories.

**B. Policy:**

**When anti-markup applies:**

Anti-markup applies when a diagnostic service payable under the Medicare Physician Fee Schedule (MPFS) is performed by one physician/supplier and billed by another physician/supplier. The conditions that must exist to establish whether the anti-markup applies is discussed below.

The anti-markup payment limitation **will apply** in cases where a physician does not share a practice with the billing physician or other supplier, either under the "substantially all services" or "site of service" test defined below**.**

Payment to the billing physician or other supplier (less the applicable deductibles and coinsurance paid by or on behalf of the beneficiary) for the TC or PC of the diagnostic test may not exceed the lowest of the following amounts:

(i) The performing supplier's net charge to the billing physician or other supplier.
(ii) The billing physician or other supplier's actual charge.
(iii) The fee schedule amount for the test that would be allowed if the performing supplier billed directly (42 CFR § 414.50(a)(1)).

The net charge must be determined without regard to any charge that reflects the cost of equipment or space leased to the performing supplier by the billing physician or other supplier (42 CFR § 414.50(a)(2)(i)).

The provision of Publication 100-04, Chapter 16, §40.2 still applies, thus this new anti-markup provision does not apply to independent laboratories.

**When anti-markup does not apply:**

The anti-markup payment limitation **will not apply** if the performing physician "shares a practice" with the billing physician or other supplier. As set forth in 42 CFR § 414.50(a)(2), there are two alternatives for determining whether a performing/supervising physician shares a practice with the billing physician or other supplier.

**Alternative one; substantially all services requirement:**

Under the first alternative, if the performing physician (that is, the physician who supervises the TC or performs the PC, or both) furnishes substantially all (at least 75 percent) of his or her professional services through the billing physician or other supplier, none of the physician's diagnostic testing services will be subject to the anti-markup payment limitation. If the performing physician does not meet the "substantially all services" requirement, a "site of service" analysis may be applied on a test-by-test basis to determine whether the anti-markup payment limitation applies.

**Alternative two; site of service test:**

The second alternative is the "site of service" test. Only TCs conducted and supervised and PCs performed in the "office of the billing physician or other supplier" by a physician owner, employee or independent contractor of the billing physician or other supplier will avoid application of the anti-markup payment limitation.

The "office of the billing physician or other supplier" is any medical office space, regardless of the number of locations, in which the ordering physician regularly furnishes patient care. This includes space where the billing physician or other supplier furnishes diagnostic testing, if the space is located in the "same building" (as defined in 42 CFR § 411.351) in which the ordering physician regularly furnishes patient care.

If the billing physician or other supplier is a physician organization (as defined in 42 CFR § 411.351), the "office of the billing physician or other supplier" is space in which the ordering physician provides substantially the full range of patient care services that the ordering physician generally provides.

With respect to the TC, the performing supplier is the physician that supervised the TC and, with respect to the PC, the performing supplier is the physician that performed the PC.

**Billing instructions:**

More than one test subject to the anti-markup payment limitation (an "anti-markup test") may be billed on the ANSI X12N 837P electronic format. When more than one test is billed, the total anti-markup service amount

must be submitted for each service. Treat claims received with multiple anti-markup tests without line level total anti-markup (purchased service) amount information as unprocessable per Publication 100-04, Chapter 1, § 80.3.2.

Treat paper claims submitted for anti-markup tests with more than one diagnostic service with either a 26 or TC modifier on the claim as unprocessable. When billed using the Form CMS-1500, each component of the test must be submitted on a separate claim form. Claims submitted on the Form CMS-1500 with more than one service with a 26 or TC modifier and item 20 indicating that an anti-markup test is being billed are to be treated as unprocessable per Publication 100-04, Chapter 1, §80.3.2.

ANSI X12N 837P electronic claims submitted with multiple anti-markup tests on the same claim must be accepted. Assume that the claim level service facility location information applies to a billed diagnostic service with a CPT/HCPCS modifier 26 or TC if line level information is not provided.

In order to price claims correctly and apply purchase price limitations, global billing is not acceptable for anti-markup claims received on the Form CMS-1500 or in the ANSI X12N 837P electronic format. Each component must be billed separately. Treat the claim as unprocessable per Publication 100-04, Chapter 1, §80.3.2, when a global billing is received and there is information on the claim that indicates the test was anti-markup test.

## II. BUSINESS REQUIREMENTS TABLE

*"Shall" denotes 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 | |
| 6371.1 | Contractors shall accept, and process accordingly, claims for either the technical component (TC) or the professional component (PC) of diagnostic tests (other than clinical diagnostic laboratory tests) submitted with the proper coding in the Purchased Service segments of the ANSI X12 837P electronic claim format | X | | | X | | | X | | | |
| 6371.2 | For diagnostic test claims submitted on a Form CMS-1500, contractors shall return as unprocessable those claims received with more than one TC or PC service charge when Item 20 of the Form CMS-1500 is marked "YES". | X | | | X | | | X | | | |
| 6371.2.1 | Contractors shall use Reason Code 125 – "Submission/billing error(s)" and Remittance Advice (RA) Remark Code M65 – "One interpreting physician charge can be submitted per claim when a purchased diagnostic test is indicated. Please submit a separate claim for each interpreting physician" when returning a claim as unprocessable according to BR 6371.2 | X | | | X | | | X | | | |
| 6371.3 | For diagnostic test claims submitted on a Form CMS-1500, contractors shall return as unprocessable those claims submitted with "YES" marked in Item 20 but no charge amount entered. | X | | | 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 | |
| 6371.3.1 | Contractors shall use Reason Code 16 – "Claim/service lacks information which is needed for adjudication" and RA Remark Code MA111 – "Missing/incomplete/invalid purchase price of the test(s) and/or the performing laboratory's name and address." when returning a claim as unprocessable according to BR 6371.3. | X | | | X | | | X | | | |
| 6371.4 | For diagnostic test claims submitted on a Form CMS-1500, contractors shall return as unprocessable those claims received with the "YES" indicator checked and a dollar amount in Item 20 but no location information (name, address, city, state, and ZIP) for the physician/supplier from whom the diagnostic test was acquired in Item 32. | X | | | X | | | X | | | |
| 6371.4.1 | Contractors shall use Reason Code 16 – "Claim/service lacks information which is needed for adjudication" and RA Remark Code N294 – "Missing/incomplete/invalid service facility primary address" when returning a claim as unprocessable according to BR 6371.5. | X | | | X | | | X | | | |
| 6371.5 | For diagnostic test claims submitted on a Form CMS-1500 with Item 20 marked "YES" and also including a charge amount in Item 20, contractors shall use the "anti-markup pricing" methodology to determine the proper amount to pay for the service. | X | | | X | | | X | | | |
| 6371.5.1 | Contractors shall consider the "anti-markup pricing methodology" to be the payment amount for the TC or PC portion of a diagnostic test which is the lesser of:<br>• the charge amount in Item 20 of the Form CMS-1500,<br>• the submitted charge of the service, or<br>• the appropriate fee schedule amount. | 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 | |
| 6371.6 | A provider education article related to this instruction will be available at | X | | | 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 | |
| | 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.<br>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. | | | | | | | | | | |

## IV. SUPPORTING INFORMATION

**A. For any recommendations and supporting information associated with listed requirements, use the box below:**
*"Should" denotes a recommendation.*

| X-Ref Requirement Number | Recommendations or other supporting information: |
|---|---|
| | |

**B. For all other recommendations and supporting information, use this space:**

## V. CONTACTS

**Pre-Implementation Contact(s):** Contact Eric Coulson at (410)786-3352 or by email at Eric.Coulson@cms.hhs.gov

**Post-Implementation Contact(s):** For questions concerning policies concerning the anti-markup payment limitations, contact David Walczak at (410)786-4475 or by email at David.Walczak@cms.hhs.gov. For questions concerning the billing instructions related to billing for diagnostic tests subject to anti-markup payment limitations, contact Eric Coulson at (410)786-3352 or by email at Eric.Coulson@cms.hhs.gov

## VI. FUNDING

**A. For *Fiscal Intermediaries and 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.

**B. *For Medicare Administrative Contractors (MACs),* use 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.