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| <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 1418</b>                      | <b>Date: JANUARY 18, 2008</b>                             |
|  | <b>Change Request 5805</b>                                |

**SUBJECT: New HCPCS Modifiers when Billing for Patient Care in Clinical Research Studies**

**I. SUMMARY OF CHANGES:** CMS is discontinuing the QA, QR, and QV HCPCS modifiers and creating Q0 and Q1 to identify investigational and routine clinical services provided in a clinical research study approved by Medicare. These two new modifiers will be included in the 2008 Annual HCPCS Update. The CR is to be implemented no later than April 7, 2008.

**New / Revised Material**

**Effective Date: January 1, 2008**

**Implementation Date: No Later Than April 7, 2008**

*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     | 1/80.3.2.1.3/Carrier Specific Requirements for Certain Specialties/Services                                    |
| R     | 32/68.3/Billing Requirements for Providers Billing Routine Costs of Clinical Trials Involving a Category A IDE |
| R     | 32/68.4/Billing Requirements for Providers Billing Routine Costs of Clinical Trials Involving a Category B IDE |
| R     | 32/69.6/Billing Requirements for Clinical Trials   |
| R     | 32/69.7/Reserved for Future Use  |

### **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:**

**Business Requirements**

**Manual Instruction**

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

# Attachment – Business Requirements

|             |                   |                        |                      |
|-------------|-------------------|------------------------|----------------------|
| Pub. 100-04 | Transmittal: 1418 | Date: January 18, 2008 | Change Request: 5805 |
|-------------|-------------------|------------------------|----------------------|

**SUBJECT: New HCPCS Modifiers when Billing for Patient Care in Clinical Research Studies**

**Effective Date:** January 1, 2008

**Implementation Date:** No Later Than April 7, 2008

## I. GENERAL INFORMATION

**A. Background:** The current, 2007 Annual HCPCS Update contains the following three modifiers to bill for patient care when beneficiaries are enrolled in clinical research studies (formerly referred to as clinical trials):

- QA - FDA Investigational Device Exemption.
- QR - Item or Service Provided in a Medicare Specified Study.
- QV - Item or Service Provided as Routine Care in a Medicare Qualifying Clinical Trial.

It has come to our attention that these modifiers are not being used as intended as the long descriptors are vague and overlapping. As a result, the Centers for Medicare and Medicaid Services (CMS) is revising its modifier coding policy.

**B. Policy:** CMS is discontinuing the QA, QR, and QV modifiers as of December 31, 2007, and creating the following two new modifiers that will be used solely to differentiate between routine and investigational clinical services. These new modifiers will be included in the 2008 Annual HCPCS Update and are effective for dates of service on and after January 1, 2008:

- Q0 - Investigational clinical service provided in a clinical research study that is in an approved clinical research study.
  - Investigational clinical services are defined as those items and services that are being investigated as an objective within the study. Investigational clinical services may include items or services that are approved, unapproved, or otherwise covered (or not covered) under Medicare.
- Q1 - Routine clinical service provided in a clinical research study that is in an approved clinical research study.
  - Routine clinical services are defined as those items and services that are covered for Medicare beneficiaries outside of the clinical research study; are used for the direct patient management within the study; and, do not meet the definition of investigational clinical services. Routine clinical services may include items or services required solely for the provision of the investigational clinical services (e.g., administration of a chemotherapeutic agent); clinically appropriate monitoring, whether or not required by the investigational clinical service (e.g., blood tests to measure tumor markers); and items or services required for the prevention, diagnosis, or treatment of research related adverse events (e.g., blood levels of various parameters to measure kidney function).

Contractors are to update their edits as follows:

- The Q0 modifier replaces QA and QR.

- The Q1 modifier replaces QV.

All claims submitted for patient care in clinical research studies must use the two new modifiers for routine and investigational clinical services. This includes studies that are certified under the Medicare Clinical Research Policy, Investigational Device Exemption (IDE) trials, and studies required under a coverage with evidence development (CED) national coverage determination (NCD). Effective for dates of service on and after January 1, 2008, claims submitted with the discontinued modifiers will be processed as return-to-provider/return as unprocessable.

## II. BUSINESS REQUIREMENTS TABLE

Use "Shall" to denote a mandatory requirement

| Number   | Requirement  | Responsibility (place an "X" in each applicable column) |                            |        |                                 |                  |                              |             |             |   |             |
|----------|--|---|----------------------------|--------|---------------------------------|------------------|------------------------------|-------------|-------------|---|-------------|
|          |  | A<br>/<br>B<br>M<br>A<br>C                              | D<br>M<br>E<br>M<br>A<br>C | F<br>I | C<br>A<br>R<br>R<br>I<br>E<br>R | R<br>H<br>I      | Shared-System<br>Maintainers |             |             |   | OTHER       |
|          |  |   |                            |        |                                 | F<br>I<br>S<br>S | M<br>C<br>S                  | V<br>M<br>S | C<br>W<br>F |   |             |
| 5805.1   | Effective for dates of service on or after January 1, 2008, contractors accept the two new modifiers Q0 and Q1 used for clinical research studies.<br><br><b>NOTE:</b> The two new modifiers will be part of the 2008 Annual HCPCS Update.   | X   | X                          | X      | X                               | X                | X                            |             | X           | X | COBC<br>NCH |
| 5805.2   | Effective for dates of service on or after January 1, 2008, contractors shall create new edits, and/or modify existing edits, per the following HCPCS update: <ul style="list-style-type: none"> <li>• The Q0 modifier replaces the QA and QR modifiers</li> <li>• The Q1 modifier replaces the QV modifier</li> </ul> | X   | X                          | X      | X                               | X                | X                            | X           | X           |   |             |
| 5805.3   | Contractors shall educate via a MLN article that if a Category A or B investigational device is used in the clinical trial, they should continue to place the IDE number in item 23 of the CMS-1500 or electronic equivalent and place modifier Q0 on the claim.   | X   |                            |        | X                               |                  |                              |             |             |   |             |
| 5805.3.1 | Contractors shall <b>NOT</b> return claims billed with modifier Q0 that do not contain an IDE number in item 23 of the CMS-1500 form or the electronic equivalent.   | X   | X                          |        | X                               |                  |                              | X           | X           |   |             |
| 5805.4   | The standard system maintainer shall develop hard coded EDS controlled edits for IDE number validation when the modifier Q0 and the IDE # for either a Category A or B device appears on the claim.  |   |                            |        |                                 |                  |                              | X           |             |   |             |
| 5805.4.1 | The standard system maintainer shall validate an exact match on the IDE # if Q0 is present on an IDE claim.  |   |                            |        |                                 |                  |                              | X           |             |   |             |
| 5805.4.2 | The standard system maintainer shall validate that the date of service (DOS) on the claim service line   |   |                            |        |                                 |                  |                              | X           |             |   |             |

| Number   | Requirement   | Responsibility (place an "X" in each applicable column) |                                |        |                                 |                  |                           |             |             |             |       |
|----------|---|---|--------------------------------|--------|---------------------------------|------------------|---------------------------|-------------|-------------|-------------|-------|
|          |   | A<br>/<br>B<br><br>M<br>A<br>C                          | D<br>M<br>E<br><br>M<br>A<br>C | F<br>I | C<br>A<br>R<br>R<br>I<br>E<br>R | R<br>H<br>H<br>I | Shared-System Maintainers |             |             |             | OTHER |
|          |   |   |                                |        |                                 |                  | F<br>I<br>S<br>S          | M<br>C<br>S | V<br>M<br>S | C<br>W<br>F |       |
|          | containing the Q0 falls within the DOS on the IDE file.   |   |                                |        |                                 |                  |                           |             |             |             |       |
| 5805.4.3 | Contractors shall return the claim as unprocessable if the claim with a Q0 modifier and IDE # does not meet the criteria in BR 4, 4.1, 4.2. (Use Reason Code 16 along with Remark code MA50.) | X   |                                |        | X                               |                  |                           |             |             |             |       |
| 5805.5   | Contractors shall not search files for claims already processed but should adjust claims brought to their attention.  | X   | X                              | X      | X                               |                  |                           |             |             |             |       |

### III. PROVIDER EDUCATION TABLE

| Number | Requirement  | Responsibility (place an "X" in each applicable column) |                                |        |                                 |                  |                           |             |             |             |       |
|--------|--|---|--------------------------------|--------|---------------------------------|------------------|---------------------------|-------------|-------------|-------------|-------|
|        |  | A<br>/<br>B<br><br>M<br>A<br>C                          | D<br>M<br>E<br><br>M<br>A<br>C | F<br>I | C<br>A<br>R<br>R<br>I<br>E<br>R | R<br>H<br>H<br>I | Shared-System Maintainers |             |             |             | OTHER |
|        |  |   |                                |        |                                 |                  | F<br>I<br>S<br>S          | M<br>C<br>S | V<br>M<br>S | C<br>W<br>F |       |
| 5805.6 | <p>A provider education article related to this instruction will be available at <a href="http://www.cms.hhs.gov/MLNMMattersArticles">http://www.cms.hhs.gov/MLNMMattersArticles</a> shortly after the CR is released. You will receive notification of the article release via the established "MLN Matters" listserv.</p> <p>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.</p> | X   | X                              | X      | X                               | X                |                           |             |             |             |       |

### IV. SUPPORTING INFORMATION

**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: |
|--------------------------|--|
|                          |  |

| 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):**

National Coverage Determination: Leslye Fitterman, [leslye.fitterman@cms.hhs.gov](mailto:leslye.fitterman@cms.hhs.gov), 410-786-3669  
 Institutional Claims Processing: Joe Bryson, [joseph.bryson@cms.hhs.gov](mailto:joseph.bryson@cms.hhs.gov), 410-786-2986 or  
 Valeri Ritter, [valeri.ritter@cms.hhs.gov](mailto:valeri.ritter@cms.hhs.gov), 410-786-8652  
 Physician Claims Processing: Vera Dillard, [vera.dillard@cms.hhs.gov](mailto:vera.dillard@cms.hhs.gov), 410-786-6149  
 DME Claims Processing: Tracey Hemphill, [tracey.hemphill@cms.hhs.gov](mailto:tracey.hemphill@cms.hhs.gov), 410-786-7169

**Post-Implementation Contact(s):** Appropriate CMS RO

**VI. FUNDING**

**A.** No additional funding will be provided by CMS; contractor activities are to be carried out within their operating budgets.

**B.** The contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the Statement of Work (SOW). 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.

# Medicare Claims Processing Manual

## Chapter 1 - General Billing Requirements

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### 80.3.2.1.3 - Carrier Specific Requirements for Certain Specialties/Services

*(Rev. 1418, Issued: 01-18-08, Effective: 01-01-08, Implementation: 04-07-08)*

Carriers must return the following claim as unprocessable to the provider of service/supplier:

a. For chiropractor claims:

1. If the x-ray date is not entered in item 19 for claims with dates of service prior to January 1, 2000. Entry of an x-ray date is not required for claims with dates of service on or after January 1, 2000.

2. If the initial date “actual” treatment occurred is not entered in item 14. (Remark code MA122 is used.)

b. For certified registered nurse anesthetist (CRNA) and anesthesia assistant (AA) claims, if the CRNA or AA is employed by a group (such as a hospital, physician, or ASC) and the group’s name, address, ZIP code, and PIN number, *until the NPI is required*, is not entered in item 33 or if the NPI is not entered in item 33a. of the *Form CMS-1500 (8/05)* when the NPI is *required* or, *until the NPI is required*, if their personal PIN is not entered in item 24K of the *Form CMS-1500 (12-90)* or if the NPI is not entered into item 24J of the *Form CMS-1500 (8/05)* when the NPI is *required*. (Remark code MA112 is used.)

c. For durable medical, orthotic, and prosthetic claims, if the name, address, and ZIP code of the location where the order was accepted were not entered in item 32. (Remark code MA 114 is used.)

d. For physicians who maintain dialysis patients and receive a monthly capitation payment:

1. If the physician is a member of a professional corporation, similar group, or clinic, and, *until the NPI is required*, the attending physician’s PIN is not entered in item 24K of the *Form CMS-1500 (12-90)* or if the NPI is not entered into item 24J of the *Form CMS-1500 (8/05)* when the NPI is *required*. (Remark code N290 is used.)

2. If the name, address, and ZIP code of the facility other than the patient’s home or physician’s office involved with the patient’s maintenance of care and training

is not entered in item 32. (Remark code MA114 is used.) Effective for claims received on or after April 1, 2004, the name, address, and ZIP code of the service location for all services other than those furnished in place of service home – 12 must be entered.

e. For routine foot care claims, if the date the patient was last seen and the attending physician's PIN (or NPI when *required*) is not present in item 19. (Remark code N324 or N253 is used.)

f. For immunosuppressive drug claims, if a referring/ordering physician, physician's assistant, nurse practitioner, clinical nurse specialist was used and their name is not present in items 17 *or their UPIN (until the NPI is required) is not present in 17a.* or if the NPI is not entered in item 17b. of the *Form CMS-1500 (8/05)* when the NPI is *required.* (Remark code N264 or N286 is used.)

g. For all laboratory services, if the services of a referring/ordering physician, physician's assistant, nurse practitioner, clinical nurse specialist are used and his or her name is not present in items 17 *or their UPIN (until the NPI is required) is not present in 17a.* or if the NPI is not entered in item 17b. of the *Form CMS-1500 (8/05)* when the NPI *is required.* (Remark code N264 or N286 is used.)

h. For laboratory services performed by a participating hospital-leased laboratory or independent laboratory in a hospital, clinic, laboratory, or facility other the patient's home or physician's office (including services to a patient in an institution), if the name, address, and ZIP code of the location where services were performed is not entered in item 32. (Remark code MA114 is used.) Effective for claims received on or after April 1, 2004, the name, address, and ZIP code of the service location for all services other than those furnished in place of service home – 12 must be entered.

i. For independent laboratory claims:

1. Involving EKG tracing and the procurement of specimen(s) from a patient at home or in an institution, if the claim does not contain a validation from the prescribing physician that any laboratory service(s) performed were conducted at home or in an institution by entering the appropriate annotation in item 19 (i.e., "Homebound"). (Remark code MA116 is used.)

2. If the name, address, and ZIP code where the test was performed is not entered in item 32, if the services were performed in a location other than the patient's home or physician's office. (Remark code MA114 is used.) Effective for claims received on or after April 1, 2004, the name, address, and ZIP code of the service location for all services other than those furnished in place of service home – 12 must be entered.

j. For mammography “diagnostic” and “screening” claims, if a qualified screening center does not accurately enter their 6-digit, FDA-approved certification number in item 32 when billing the technical or global component. (Remark code MA128 is used.)

k. For parenteral and enteral nutrition claims, if the services of an ordering/referring physician, physician assistant, nurse practitioner, clinical nurse specialist are used and their name is not present in item 17 *or their UPIN (until the NPI is required) is not present in item 17a.* or if the NPI is not entered in item 17b. of the Form CMS-1500 (8/05) when the NPI is *required*. (Remark code N264 or N286 is used.)

l. For portable x-ray services claims, if the ordering physician, physician assistant, nurse practitioner, clinical nurse specialist’s name, and/or UPIN (or NPI when *required*) is not entered in items 17 *or their UPIN (until the NPI is required) is not entered in item 17a.* or if the NPI is not entered in item 17b. of the Form CMS-1500 (8/05) when the NPI is *required*. (Remark code N264 or N286 is used.)

m. For radiology and pathology claims for hospital inpatients, if the referring/ordering physician, physician assistant, nurse practitioner, *or* clinical nurse specialist’s name, if appropriate, *is* not entered in items or 17 *or their UPIN (until the NPI is required) is not entered in item 17a.* or if the NPI is not entered in item 17b. of the Form CMS-1500 (8/05) when the NPI is *required*. (Remark code N264 or N286 is used.)

n. For outpatient physical or occupational therapy services provided by a qualified, independent physical, or occupational therapist, Medicare policy does not require the date last seen by a physician, or the UPIN *or* NPI, *when required*, of such physician. Medicare policy does not require identification of the ordering, referring or certifying physician on outpatient therapy claims, including speech-language pathology service claims. However, providers and suppliers are required to comply with applicable HIPAA ASC X12 837 claim completion requirements. See Pub. 100-04, chapter 5, §20 and Pub. 100-02, chapter 15, §§220 and 230 for therapy service policies. Deletion of this claim requirement for outpatient therapy services does not apply to the requirements for the date last seen and the UPIN *or* NPI, *when required*, of the ordering and supervising physician/nonphysician practitioner for therapy services provided incident to the services of a physician, because the incident to policies continue to require them.

1. If the UPIN (or NPI when *required*) of the attending physician is not present in item 19. (Remark code N253 is used.)

2. If the 6-digit (MM | DD | YY) or 8-digit (MM | DD | CCYY) date patient was last seen by the attending physician is not present in item 19. (Remark code N324 is used.)

o. For all laboratory work performed outside a physician’s office, if the claim does not contain a name, address, and ZIP code, and PIN (*until the NPI is required*) where the laboratory services were performed in item 32 or if the NPI is not entered into item 32a.

of the Form CMS-1500 (8/05) when the NPI is *required*), if the services were performed at a location other than the place of service home – 12. (Use Remark code MA114.)

p. For all physician office laboratory claims, if a 10-digit CLIA laboratory identification number is not present in item 23. This requirement applies to claims for services performed on or after January 1, 1998. (Remark code MA120 is used.)

q. For investigational devices billed in an FDA-approved clinical trial if an Investigational Device Exemption (IDE) number is not present in item 23, *for dates of service through March 31, 2008*. (Remark code MA50 is used.) *With the use of new modifier Q0, effective for dates of service on and after April 1, 2008, contractors will no longer be able to distinguish an IDE claim from other investigational clinical services. Therefore this edit will no longer apply.*

r. For physicians performing care plan oversight services if the 6-digit Medicare provider number of the home health agency (HHA) or hospice is not present in item 23. (Remark code MA49 is used.)

s. For Competitive Acquisition Program drug and biological claims, in accordance with the instructions found in the Medicare Claims Processing Manual, Chapter 17, Section 100.4.2 through 100.4.4.

# Medicare Claims Processing Manual

## Chapter 32 – Billing Requirements for Special Services

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### Table of Contents (Rev. 1418, 01-18-08)

69.6 – *Billing Requirements for Clinical Trials*

69.7 – *Reserved for Future Use*

### **68.3 – Billing Requirements for Providers Billing Routine Costs of Clinical Trials Involving a Category A IDE**

*(Rev. 1418, Issued: 01-18-08, Effective: 01-01-08, Implementation: 04-07-08)*

Providers shall notify their contractor of the Category A IDE device trial before billing routine costs of clinical trials involving a Category A device, as listed in Section 68.2 above. Upon receiving the required information for the trial, the contractor will determine if the Category A device, as used in the trial, is intended for the diagnosis, monitoring, or treatment of an immediately life-threatening disease/condition. If the contractor determines that the device does, in fact, meet the requirements of coverage, then the provider may begin billing the routine costs of a clinical trial involving a Category A device.

Providers shall submit claims for the routine costs of a clinical trial involving a Category A IDE by billing according to the clinical trial billing instructions found in [Section 69.6](#) (Qualifying Clinical Trials) of this chapter.

In addition to billing the routine costs, providers must identify the line for which the Category A IDE device is being billed.

#### ***Institutional Billing***

Institutional providers must bill the device involved with the clinical trial by placing the Category A IDE Number on a 0624 (IDE) revenue code line, with the charges for the device placed in the “Non-covered” charges field. The 0624 revenue code and the **Q0** modifier alert contractors that the Category A IDE is billed on that line.

#### ***Practitioner/Supplier Billing***

*Effective for dates of service on or before December 31, 2007, practitioner/supplier providers must place a QV modifier (Item or service provided as routine care in a Medicare qualifying clinical trial) on the line for the device **along with the IDE number.***

*Effective for dates of service on or after January 1, 2008, practitioner/suppliers will no longer bill a QV modifier to identify the device. Instead, practitioner/suppliers will bill a Q0 modifier (Investigational clinical service provided in a clinical research study that is in an approved clinical research study) along with the IDE number.*

**68.4 – Billing Requirements for Providers Billing Routine Costs of Clinical Trials Involving a Category B IDE**  
*(Rev. 1418, Issued: 01-18-08, Effective: 01-01-08, Implementation: 04-07-08)*

As noted above in section 68.2, of this chapter, providers shall first notify their contractor of the IDE device trial before submitting claims for Category B IDEs. Once the contractor notifies the provider that all required information for the IDE has been furnished, the provider may bill claims for the particular Category B IDE.

When billing for Category B IDEs, providers shall bill for the device and all related procedures. *The Category B IDE and the routine costs associated with its use are eligible for payment under Medicare. (Reimbursement for the device may not exceed the Medicare-approved amount for a comparable device that has been already FDA-approved).*

***Institutional Billing***

Institutional providers must bill the Category B IDE Number on a 0624 revenue code line with charges in the covered charges field (providers receiving the device free of charge must bill the IDE charges as non-covered).

***Practitioner/Supplier Billing***

*Effective for dates of service on or before December 31, 2007, practitioners/suppliers must bill the Category B IDE on a line with a QA modifier (FDA IDE) along with the IDE number. However, effective for dates of service on or after January 1, 2008, practitioner/suppliers will no longer bill a QA modifier to identify a Category B device. Instead, practitioners/suppliers will bill a Q0 modifier (Investigational clinical service provided in a clinical research study that is in an approved clinical research study) along with the IDE number.*

The following table shows the designated field locations to report the IDE Number on institutional and practitioner claims:

| <b>Data</b> | <b>CMS-1450</b>       | <b>CMS-1500</b>         | <b>837i and 837p</b>                      |
|-------------|-----------------------|-------------------------|---|
| IDE #       | <a href="#">FL 43</a> | <a href="#">Item 23</a> | Segment 2300,<br>REF02( <i>REF01=LX</i> ) |

*Contractors will validate the IDE number for either a Category A or B device when modifier Q0 is submitted on the claim along with the IDE number. Claims containing an invalid IDE number will be returned to the provider. (Remark code MA50 is used,*

*Missing/incomplete/invalid Investigational Device Exemption Number for FDA approved clinical trial services), along with Reason Code 16 (Claim/service lacks information which is needed for adjudication).*

## **69.6 - Billing Requirements for Clinical Trials**

**(Rev. 1418, Issued: 01-18-08, Effective: 01-01-08, Implementation: 04-07-08)**

### Routine Costs Submitted by Practitioners/Suppliers:

*Services* furnished to Medicare beneficiaries, who are control group volunteers participating in qualifying clinical trials, are to be coded/billed in the following manner:

#### *Claims with dates of service before January 1, 2008:*

- *HCPCS modifier “QV”*
- Diagnosis code V70.7 (Examination of participant in clinical trial) reported as the primary diagnosis

#### *Claims with dates of service on or after January 1, 2008:*

- *HCPCS modifier ‘Q1’*
- Diagnosis code V70.7 (Examination of participant in clinical trial) reported as the primary diagnosis

If the QV *or* Q1 modifier is billed and diagnosis code V70.7 is submitted by practitioners as a secondary rather than the primary diagnosis, do not consider the service as having been furnished to a diagnostic trial volunteer. Instead, process the service as a therapeutic clinical trial service.

*Effective for clinical trial claims received after April 1, 2008, (regardless of the date of service) providers can begin to report an 8 digit clinical trial number. The reporting of this number is voluntary at this time. Refer to change request 5790 for more information regarding the 8 digit number. Below are the claim locators that providers should use to bill the 8 digit number:*

- *CMS-1500 paper form-place in Field 19 (preceded by ‘CT’)*
- *837 P—Loop 2300, REF02, REF01-P4 (do not use “CT” on the electronic claim).*

### Routine Costs Submitted by Institutional Providers:

*Services* furnished to Medicare beneficiaries, who are control group volunteers participating in qualifying diagnostic clinical trials, are to be coded/billed on the in the following manner:

#### *Claims with dates of service before January 1, 2008:*

- Condition code 30 (qualifying clinical trial) is reported at the claim level

- *HCPCS modifier 'QV'* (only for *institutional* outpatient claims)
- Diagnosis code V70.7 (Examination of participant in clinical trial) reported as the secondary diagnosis

*Claims with dates of service on or after January 1, 2008:*

- Condition code 30 (qualifying clinical trial) is reported at the claim level
- *HCPCS modifier 'Q1'* (only for *institutional* outpatient claims)
- Diagnosis code V70.7 (Examination of participant in clinical trial) reported as the secondary diagnosis

*Effective for clinical trial claims received after April 1, 2008, (regardless of date of service) providers can begin to report an 8 digit clinical trial number. The reporting of this number is voluntary at this time. Refer to change request 5790 for more information regarding the 8 digit number. To bill the 8 digit clinical trial number, institutional providers shall code value code 'D4' ---where the value code amount equals the 9 digit clinical trial number. Below are the claim locators in which to bill the 8 digit number:*

- *CMS-1450—Form Locator 39-41*
- *837I-Loop 2300 HI – VALUE INFORMATION segment (qualifier BE)*

**NOTE:** The QV/*Q1* modifier is line item specific and must be used to identify items and services that constitute medically necessary routine patient care or treatment of complications arising from a Medicare beneficiary's participation in a Medicare covered clinical trial. Items and services that are provided solely to satisfy data collection and analysis needs and that are not used in the clinical management of the patient are not covered and may not be billed using the QV/*Q1* modifier. Items and services that are not covered by Medicare by virtue of a statutory exclusion or lack of a benefit category also may not be billed using the QV/*Q1* modifier. When billed in conjunction with the V70.7 diagnosis code, the QV/*Q1* modifier will serve as the provider's attestation that the service meets the Medicare coverage criteria (i.e., was furnished to a beneficiary who is participating in a Medicare qualifying clinical trial and represents routine patient care, including complications associated with qualifying trial participation).

**69.7 – *Reserved for Future Use***

***(Rev. 1418, Issued: 01-18-08, Effective: 01-01-08, Implementation: 04-07-08)***