

<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 2955</b>	<b>Date: May 14, 2014</b>
	<b>Change Request 8401</b>

**Transmittal 2805, dated October 30, 2013, has been rescinded and replaced by Transmittal 2955, dated May 13, 2014, to remove BR 8401.1 and to add reference to the corresponding MedLearn Matters Articles. All other information remains the same.**

**SUBJECT: Mandatory Reporting of an 8-Digit Clinical Trial Number on Claims**

**I. SUMMARY OF CHANGES:** The purpose of this change request (CR) is to inform providers and suppliers that effective January 1, 2014, it will be mandatory to report a clinical trial number on claims for items/services provided in clinical trials that are qualified for coverage as specified in the Medicare National Coverage Determination (NCD) Manual, Publication 100-03, section 310.1. The clinical trial number that the Centers for Medicare & Medicaid Services (CMS) is making mandatory is the same number that has been reported voluntarily since the implementation of CR5790, TR310, dated January 18, 2008 - the number assigned by the National Library of Medicine (NLM) ClinicalTrials.gov website when a new study appears in the NLM Clinical Trials data base.

**EFFECTIVE DATE: January 1, 2014**

**IMPLEMENTATION DATE: January 6, 2014**

*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.*

<b>R/N/D</b>	<b>CHAPTER / SECTION / SUBSECTION / TITLE</b>
R	32/68/1/General
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	32/69/2/Payment for Qualifying Clinical Trial Services
R	32/69/5/Billing Requirments - General
R	32/69/6/Requirements for Billing Routine Costs of Clinical Trials

**III. FUNDING:**

**For Fiscal Intermediaries (FIs), Regional Home Health Intermediaries (RHHIs) and/or Carriers:**

No additional funding will be provided by CMS; Contractors activities are to be carried out with 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 obliged 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: 2955	Date: May 14, 2014	Change Request: 8401
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**SUBJECT: Mandatory Reporting of an 8-Digit Clinical Trial Number on Claims**

**EFFECTIVE DATE: January 1, 2014**

**IMPLEMENTATION DATE: January 6, 2014**

## I. GENERAL INFORMATION

**A. Background:** The purpose of this change request (CR) is to inform providers and suppliers that effective January 1, 2014, it will be mandatory to report a clinical trial number on claims for items/services provided in clinical trials that are qualified for coverage as specified in the Medicare National Coverage Determination (NCD) Manual, Publication 100-03, section 310.1. The clinical trial number that the Centers for Medicare & Medicaid Services (CMS) is making mandatory is the same number that has been reported voluntarily since the implementation of CR5790, TR310, dated January 18, 2008, the number assigned by the National Library of Medicine (NLM) ClinicalTrials.gov website when a new study appears in the NLM Clinical Trials data base. This number is listed prominently on each specific study's page and is always preceded by the letters "NCT." CMS uses this number to identify all items/services provided to beneficiaries during their participation in a clinical trial, clinical study, or registry that may result from a study covered under coverage with evidence development (CED), the Medicare Clinical Trial Policy, or a CMS-approved investigational device exemption (IDE) study.

Furthermore, this identifier permits CMS to better track Medicare payments, ensure that the information gained from the research is used to inform coverage decisions, make certain that the research focuses on issues of importance to the Medicare population. Contractors will continue to verify the validity of a trial/study/registry by consulting CMS's clinical trials/registry website at:

<http://www.cms.gov/Medicare/Medicare-General-Information/MedicareApprovedFacilitie/index.html>

**B. Policy:** Current Medicare contractor systems shall be modified to require the 8-digit clinical trial number that was previously voluntary on all relative claims. Claims submitted without the clinical trial number that were once paid will now be returned for reprocessing/returned to provider for inclusion of the trial number.

**NOTE:** This is a reminder/clarification that clinical trials that are also IDE trials must continue to report the associated IDE number on the claim form.

**NOTE:** See the corresponding MedLearn Matters Articles for CR8401 (MM8401 dated 1/2/14, SE1344 revised 4/1/14), as well as CR3548/TR131 dated 12/17/04, CR5790/TR310 dated 1/18/08, CR5805/TR1418 dated 1/18/08, CR5719/TR74 dated 9/7/07, and CR6776/TR1901 dated 1/29/10, Pub. 100-02, Benefit Policy Manual chapter 14, section 50, Pub. 100-03, NCD Manual, chapter 1, section 310.1, and Pub. 100-04, Claims Processing Manual, chapter 32, sections 68.3, 69.6-69.7 for further supporting information relative to processing clinical trial claims.

## II. BUSINESS REQUIREMENTS TABLE

*"Shall" denotes a mandatory requirement, and "should" denotes an optional requirement.*

Number	Requirement	Responsibility
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		A/B MAC			D M E M A C	F I E L D	C A R D I E R	R H I	Shared- System Maintainers				Other
		A	B	H H H					F I S S	M C S	V M S	C W F	
8401.1	<b>This requirement deleted.</b>												
8401.2	Effective for clinical trial/registry/study claims with dates of service on and after January 1, 2014, contractors shall modify their existing edit to require the numeric, 8-digit clinical trial registry number in the electronic claim equivalent, 837I (Loop 2300 REF02 (REF01=P4) for an 837I claim when a clinical trial claim includes the following: <ol style="list-style-type: none"> <li>condition code 30,</li> <li>ICD-9 dx code V70.7/ICD-10 dx code Z00.6 (in either the primary/secondary positions), and</li> <li>modifier Q0 and/or Q1 as appropriate (outpatient claims only)</li> </ol>	X						X					
8401.3	If the REF02 (REF01=P4) is greater than 2 bytes (not a demonstration code), contractors shall map/populate the information from the above business requirement to the value code “D4”/amount data for their internal claims processing purposes.	X						X					
8401.4	Contractors shall ensure value code “D4”/amount data from their internal claims processing is mapped/populated to the 837I (Loop 2300 REF02 (REF01=P4) for a coordination of benefits (COB) 837I claim.	X						X				COBC	
8401.5	Effective for clinical trial/registry/study claims with dates of service on and after January 1, 2014, contractors shall modify their existing edits to require the numeric, 8-digit clinical trial registry number preceded by the 2 alpha characters “CT” placed in Field 19 of the paper Form CMS-1500; i.e., CT12345678, or the electronic claim equivalent 837P in Loop 2300 REF02(REF01=P4) when a clinical trial claim includes the following: <ol style="list-style-type: none"> <li>ICD-9 dx code V70.7/ICD-10 dx code Z00.6 (in either the primary/secondary positions) and</li> <li>modifier Q0 and/or Q1 as appropriate (OP claims only)</li> </ol>		X		X				X	X		AdQIC	



Number	Requirement	Responsibility							
		A/B MAC			D M E	F I	C A R R I E R	R H H I	Other
		A	B	H H H	M A C				
	to this instruction will be available at <a href="http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/">http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/</a> 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 sites 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 the contractor's 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

**Section A: Recommendations and supporting information associated with listed requirements: N/A**

*"Should" denotes a recommendation.*

X-Ref Requirement Number	Recommendations or other supporting information:

**Section B: All other recommendations and supporting information: N/A**

#### V. CONTACTS

**Pre-Implementation Contact(s):** Pat Brocato-Simons, 410-786-0261 or [patricia.brocato-simons@cms.hhs.gov](mailto:patricia.brocato-simons@cms.hhs.gov) (Coverage Policy) , William Ruiz, 410-786-9283 or [william.ruiz@cms.hhs.gov](mailto:william.ruiz@cms.hhs.gov) (Intermediary Part A Claims) , Thomas Dorsey, 410-786-7434 or [thomas.dorsey@cms.hhs.gov](mailto:thomas.dorsey@cms.hhs.gov) (Practitioner Part B Claims) , Wanda Belle, 410-786-7491 or [wanda.belle@cms.hhs.gov](mailto:wanda.belle@cms.hhs.gov) (Coverage) , Wendy Knarr, [wendy.knarr@cms.hhs.gov](mailto:wendy.knarr@cms.hhs.gov) (DME Claims) , Diana Motsiopoulos, 410-786-3379 or [diana.motsiopoulos@cms.hhs.gov](mailto:diana.motsiopoulos@cms.hhs.gov) (DME Claims)

**Post-Implementation Contact(s):** Contact your Contracting Officer's Representative (COR) 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; Contractors activities are to be carried out with 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 do 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.

## **68.1 – General**

*(Rev. 2955, Issued: 05-14-14, Effective, 01-01-14, Implementation, 01-06-14)*

*The Centers for Medicare & Medicaid Services (CMS)* determines Medicare device coverage based on which category the *Food and Drug Administration (FDA)* assigns the device. Devices are either designated as a Category A *investigational device exemption (IDE)* or a Category B IDE.

**NOTE:** For purposes of these instructions, IDEs will be referred to as “studies” instead of “trials” to help distinguish clinical trial instructions from IDE study instructions.

### **Category A Devices**

Category A IDE devices are considered experimental and, therefore, are not eligible for payment. Institutional providers should not bill for Category A IDE devices, while practitioners are required to report the Category A IDE number on the claim as specified in §68.3 of this chapter (although they will not receive payment). Practitioners must report the Category A IDE number on the claim because the contractor must validate that the IDE number is part of a current clinical trial by reviewing a monthly file provided by CMS.

Effective January 1, 2005, routine costs (as described in [The National Coverage Determinations Manual, section 310.1](#)) of clinical trials involving a Category A IDE devices are covered when the Medicare contractors determine that the device is used in the trial for the diagnosis, monitoring, or treatment of an immediately life-threatening disease or condition. Both institutional providers and practitioners are required to bill for the routine costs of clinical trials involving Category A devices as specified in §68.3 of this chapter.

### **Category B Devices**

Unlike Category A devices, Category B devices are newer generations of proven technologies that have had questions about its safety and effectiveness resolved. Category B devices may be covered under Medicare as long as it meets the billing requirements listed in section 68.2 below. If the device is billed under a Category B IDE study, and it meets the billing requirements for IDEs, the device itself and the routine costs associated with its use are eligible for payment (Payment for the device may not exceed the Medicare-approved amount for a comparable device that has been already FDA-approved).

More information regarding these two categories of IDEs can be located in [The Benefit Policy Manual, Chapter 14](#).

Future updates will be issued in a Recurring Update Notification.

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

*Rev. 2955, Issued: 05-14-14, Effective, 01-01-14, Implementation, 01-06-14)*

Providers shall notify their contractor of the Category A IDE device trial before billing routine costs of the Category A IDE device trial, as listed in section 68.2 above. Upon receiving the required information for the trial, the contractor will determine if the Category A IDE 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 IDE device.

### **Institutional Inpatient Billing**

### Routine Costs

Institutional providers shall submit claims only for the routine costs of a clinical trial involving a Category A IDE device by billing according to the clinical trial billing instructions found in §69.6 of this chapter. The Category A IDE device shall not be reported on institutional claims since it is non-covered by Medicare.

## **Institutional Outpatient Billing**

### Routine Costs

Institutional providers shall submit claims only for the routine costs of a clinical trial involving a Category A IDE device by billing according to the clinical trial billing instructions found in §69.6 of this chapter. The Category A IDE device shall not be reported on institutional claims since it is non-covered by Medicare.

## **Practitioner Billing**

### Routine Costs

Practitioners shall submit claims for the routine costs of a clinical trial involving a Category A IDE device by billing according to the clinical trial billing instructions found in §69.6 of this chapter.

### Category A Device

*Effective for claims with dates of service on or after January 1, 2014, it is **mandatory** to report a clinical trial number on claims for items/services provided in clinical trials/studies/registries, or under coverage with evidence development (CED). This is the number assigned by the National Library of Medicine (NLM) ClinicalTrials.gov Website when a new study appears in the NLM Clinical Trials data base. This number is listed prominently on each specific study's page and is always preceded by the letters "NCT." Contractors verify the validity of a trial/study/registry by consulting CMS's clinical trials/registry website at: <http://www.cms.gov/Medicare/Medicare-General-Information/MedicareApprovedFacilitie/index.html>. Providers report the 8-digit number on the following claims locators:*

- CMS-1500 paper form-place in Field 19 (preceded by 'CT'); or
- 837 P—Loop 2300, REF02, REF01=P4 (do not use 'CT' on the electronic claim)

*In addition to the clinical trial number, claims shall include:*

- ICD-9 diagnosis code V70.7/ICD-10 diagnosis code Z00.6 (in either the primary/secondary positions)
- HCPCS modifier Q0 or Q1 as appropriate

*Claims submitted without a clinical trial number shall be returned as unprocessable reporting the following messages:*

*Claim Adjustment Reason Code (CARC) 16: "Claim/service lacks information which is needed for adjudication. At least one Remark Code must be provided (may be comprised of either NCPDP Reject Reason Code, or Remittance Advice Remark Code that is not an ALERT.)"*

*Remittance Advice Remark Code (RARC) MA50: "Missing/incomplete/invalid Investigational Device Exemption number for FDA-approved clinical trial services."*

*RARC MA130: "Your claim contains incomplete and/or invalid information, and no appeal rights are afforded because the claim is unprocessable. Please submit a new claim with the complete/correct information."*

### ***Group Code - Contractual Obligation (CO)***

Effective for dates of service on or before December 31, 2007, practitioners 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, practitioners will no longer bill a QV modifier to identify the device. Instead, practitioners will bill a Q0 (numeral 0 versus the letter *O*) 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 Category A IDE number on practitioner claims:

<b>Data</b>	<b>CMS-1500</b>	<b>837i and 837p</b>
IDE #	<u>Item 23</u>	Segment 2300, REF02(REF01=LX)

Contractors will validate the IDE number for the Category A 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 *using the following messages:*

*RARC MA50: "Missing/incomplete/invalid Investigational Device Exemption Number for FDA approved clinical trial services."*

*CARC 16: "Claim/service lacks information which is needed for adjudication. At least one Remark Code must be provided (may be comprised of either NCPDP Reject Reason Code, or Remittance Advice Remark Code that is not an ALERT)."*

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

***Rev. 2955, Issued: 05-14-14, Effective, 01-01-14, Implementation, 01- 06 - 14)***

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 IDE devices and the routine costs of clinical trials involving Category B IDE devices. Once the contractor notifies the provider that all required information for the IDE has been furnished, the provider may bill Category B IDE claims.

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

### **Institutional Inpatient Billing**

#### **Routine Costs**

Institutional providers shall submit claims for the routine costs of a clinical trial involving a Category B IDE device by billing according to the clinical trial billing instructions found in §69.6 of this chapter.

#### **Category B Device**

Institutional providers must bill the Category B IDE number on a 0624 revenue code line with charges in the covered charges field. Hospital inpatient providers should not bill for the Category B IDE device if receiving the device free-of-charge.

## **Institutional Outpatient Billing**

### *Routine Costs*

Institutional providers shall submit claims for the routine costs of a clinical trial involving a Category B IDE device by billing according to the clinical trial billing instructions found in section 69.6 of this chapter.

### *Category B Device*

On a 0624 revenue code line, institutional providers must bill the following for Category B IDE devices for which they incur a cost:

- Category B IDE device HCPCS code, if applicable.
- *Appropriate HCPCS modifier:*
  - *Q0 or Q1 as appropriate for claims with dates of service on or after January 1, 2014; or*
  - Q0 (numeral 0 versus the letter *O*) modifier for claims with dates of service on or after January 1, 2008; or
  - QA modifier for claims with dates of service prior to January 1, 2008.
- *Category B IDE number*
- Charges for the device billed as covered charges

**NOTE:** If the Category B IDE device is provided at no cost, *outpatient prospective payment system (OPPS)* providers must report a token charge in the covered charge field along with the applicable HCPCS modifier (i.e., modifier –FB) appended to the procedure code that reports the service to furnish the device, in instances when claims processing edits require that certain devices be billed with their associated procedures. For more information on billing ‘no cost items’ under the OPPS, refer to Chapter 4, §§20.6.9 and 61.3.1 of this manual.

## **Practitioner Billing**

### *Routine Costs*

Practitioners shall submit claims for the routine costs of a clinical trial involving a Category B IDE device by billing according to the clinical trial billing instructions found in section 69.6 of this chapter.

### *Category B Device*

*Effective for claims with dates of service on or after January 1, 2014, it is **mandatory** to report a clinical trial number on claims for items/services provided in clinical trials/studies/registries, or under CED. Providers report the 8-digit number on the following claims locators:*

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

*In addition to the clinical trial number, claims shall include:*

- *ICD-9 diagnosis code V70.7/ICD-10 diagnosis code Z00.6 (in either the primary/secondary positions)*

- HCPCS modifier Q0 or Q1 as appropriate

Claims submitted without a clinical trial number shall be returned as unprocessable reporting the following messages:

**CARC 16:** “Claim/service lacks information which is needed for adjudication. At least one Remark Code must be provided (may be comprised of either NCPDP Reject Reason Code, or Remittance Advice Remark Code that is not an ALERT.)”

**RARC MA50:** “Missing/incomplete/invalid Investigational Device Exemption number for FDA-approved clinical trial services.”

**RARC MA130:** “Your claim contains incomplete and/or invalid information, and no appeal rights are afforded because the claim is unprocessable. Please submit a new claim with the complete/correct information.”

### Group Code-Contractual Obligation (CO)

Effective for dates of service on or before December 31, 2007, practitioners must bill the Category B IDE device 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, practitioners will no longer bill a QA modifier to identify a Category B device. Instead, practitioners will bill a Q0 modifier (numeral 0 versus the letter *O*) (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 Category B IDE number on institutional and practitioner claims:

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

Contractors will validate the IDE number for the Category 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 *using the following messages:*

**RARC MA50:** “Missing/incomplete/invalid Investigational Device Exemption Number for FDA approved clinical trial services.”

**CARC 16:** “Claim/service lacks information which is needed for adjudication. At least one Remark Code must be provided (may be comprised of either NCPDP Reject Reason Code, or Remittance Advice Remark Code that is not an ALERT.)”

## 69.2 - Payment for Qualifying Clinical Trial Services

*Rev. 2955, Issued: 05-14-14, Effective, 01-01-14, Implementation, 01-06-14)*

For dates of service on or after September 19, 2000, pay for covered services furnished to beneficiaries participating in qualifying clinical trials. Payment is based on the payment methodology applicable for the service that was furnished (e.g., physician fee schedule, lab fee schedule, *durable medical equipment* fee schedule, reasonable charge, etc.). With the exception of managed care enrollees, applicable deductibles and coinsurance rules apply to clinical trial items and services. The Part A and Part B deductibles are assumed to be met for covered clinical trial services billed on a fee service basis for managed care enrollees.

*NOTE: Effective for claims with dates of service on or after January 1, 2014, it is **mandatory** to report a clinical trial number on claims for items/services provided in clinical trials/studies/registries, or under CED. This is the number assigned by the National Library of Medicine (NLM) ClinicalTrials.gov Website when a new study appears in the NLM Clinical Trials data base. This number is listed prominently on each specific study's page and is always preceded by the letters "NCT." Contractors verify the validity of a trial/study/registry by consulting CMS's clinical trials/registry website at: <http://www.cms.gov/Medicare/Medicare-General-Information/MedicareApprovedFacilities/index.html>.*

*NOTE: Contractors shall ensure value code 'D4'/amount data from their internal claims processing is mapped/populated to the 837I (Loop 2300 REF02 (REF01=P4) for a coordination of benefits 837I claim.*

## 69.5 - Billing Requirements – General

*Rev. 2955, Issued: 05-14-14, Effective, 01-01-14, Implementation, 01-06-14)*

Instruct practitioners and institutional providers to enter clinical trial and non-clinical trial services on separate line items when billing both types of services on the same claim. For services that require a Certificate of Medical Necessity (CMN), continue to require CMNs. Items and services provided free-of-charge by research sponsors generally may not be billed to be paid by Medicare, and providers are not required to submit the charge to Medicare. If it is necessary for a provider to show the items and services that are provided free-of-charge in order to receive payment for the covered routine costs (e.g. administration of a non-covered chemotherapeutic agent), providers are instructed to submit such charges as non-covered at the time of entry, while also assuring that the beneficiary is not held liable. This instruction applies to all hospitals including hospitals located in Maryland under the jurisdiction of the Health Services Cost Review Commission (HSCRC).

For OPPS claims, providers must report a token charge for a '*no cost*' item in the covered charge field along with the applicable HCPCS modifier (i.e., modifier –FB) appended to the procedure code that reports the service provided to furnish the '*no cost*' item, in instances when claims processing edits require that certain devices be billed with their associated procedures. For more information on billing '*no cost*' items under the OPPS, refer to Chapter 4, §§20.6.9 and 61.3.1 of this manual.

*NOTE: Effective for claims with dates of service on or after January 1, 2014, it is **mandatory** to report a clinical trial number on claims for items/services provided in clinical trials/studies/registries, or under CED.*

Future updates will be issued in a Recurring Update Notification.

## 69.6 - Requirements for Billing Routine Costs of Clinical Trials

*Rev. 2955, Issued: 05-14-14, Effective, 01-01-14, Implementation, 01-06-14)*

Routine Costs Submitted by Practitioners/Suppliers

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

- HCPCS modifier ‘Q1’ (numeral 1 instead of the letter i) ; and,
- *ICD-9 diagnosis* code V70.7 (Examination of participant in clinical trial) reported as the secondary diagnosis (effective September 19, 2000, diagnosis code V70.7 can be reported as either primary or secondary).

CMS covers costs of healthy volunteers in a qualified clinical trial if it meets the following conditions:

- The trial is not designed exclusively to test toxicity or disease pathophysiology.
- The trial must have therapeutic intent.
- If the trial has therapeutic interventions, it must enroll patients with diagnosed disease rather than healthy volunteers.
- If the trial is studying diagnostic interventions, it may enroll healthy patients in order to have a proper control group.

Effective for claims processed after September 28, 2009, with dates of service on or after January 1, 2008, claims submitted with modifier Q1 shall be returned as unprocessable if diagnosis code V70.7 is not submitted on the claim.

Contractors shall return the following messages:

Claims adjustment Reason Code 16: “Claim/service lacks information which is needed for adjudication. As least one Remark Code must be provided (may be comprised of either the Remittance Advice Code or NCPDP Reject Reason Code).”

Remittance Advice Remark Code M76: “Missing/incomplete/invalid diagnosis or condition.”

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 through December 31, 2013**. Refer to change request (CR) 5790 for more information regarding the 8-digit number.

*Effective for claims with dates of service on or after January 1, 2014 it is **mandatory** to report a clinical trial number on claims for items/services provided in clinical trials/studies/registries, or under CED. Providers report the 8-digit number on the following claims locators:*

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

*In addition to the clinical trial number, claims should include:*

- *ICD-9 diagnosis code V70.7/ICD-10 diagnosis code Z00.6 (in either the primary/secondary positions)*
- *HCPCS modifier Q0 or Q1 as appropriate*

*Practitioner claims submitted without a clinical trial number shall be returned as unprocessable using the following messages:*

*CARC 16: “Claim/service lacks information which is needed for adjudication. At least one Remark Code must be provided (may be comprised of either NCPDP Reject Reason Code, or Remittance Advice Remark Code that is not an ALERT.)”*

*RARC MA50: “Missing/incomplete/invalid Investigational Device Exemption number for FDA-approved clinical trial services.”*

*RARC MA130: “Your claim contains incomplete and/or invalid information, and no appeal rights are afforded because the claim is unprocessable. Please submit a new claim with the complete/correct information.”*

### *Group Code-Contractual Obligation (CO)*

#### Routine Costs Submitted by Institutional Providers

### *All Institutional Clinical Trial Claims*

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 thru December 31, 2013**. Refer to CR 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 8-digit clinical trial number. Below are the claim locators in which to bill the 8-digit number:

- *Paper CMS-1450—Form Locator 39-41 use ‘D4’*
- *837I-Loop 2300 REF02 (REF01=P4)*

**NOTE:** *Effective for claims with dates of service on or after January 1, 2014, it is mandatory to report a clinical trial number on claims for items/services provided in clinical trials/studies/registries, or under CED. Institutional claims submitted without a clinical trial number shall be return to providers.*

**NOTE:** The 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 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 Q1 modifier. When billed in conjunction with the V70.7 diagnosis code, the 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).

### *Inpatient Clinical Trial Claims*

Institutional providers billing clinical trial service(s) must report *ICD-9* diagnosis code V70.7/*ICD-10 diagnosis code Z00.6* in either the primary or secondary position and a condition code 30 regardless of whether all services are related to the clinical trial or not.

**NOTE:** HCPCS codes are not reported on inpatient claims. Therefore, the HCPCS modifier requirements (i.e., *Q0/Q1*) as outlined in the outpatient clinical trial section immediately below, are not applicable to inpatient clinical trial claims.

### *Outpatient Clinical Trial Claims*

On all outpatient clinical trial claims, providers need to do the following:

- Report condition code 30,
- Report *ICD-9* diagnosis code V70.7/*ICD-10 diagnosis code Z00.6* in the primary or secondary *position*; and
- Identify all lines that contain an investigational item/service with a HCPCS modifier of:

- Q0 for dates of service on or after 1/1/08
- Identify all lines that contain a routine service with a HCPCS modifier of:
  - Q1 for dates of service on or after 1/1/08.

For clinical trial billing requirements for patients enrolled in a managed care plan, please refer to Section 69.9 of this chapter.