CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-04 Medicare Claims Processing	Centers for Medicare & Medicaid Services (CMS)
Transmittal 2261	**Date: JULY 29, 2011**
	Change Request 7516

SUBJECT: Affordable Care Act - Section 3113 - Laboratory Demonstration for Certain Complex Diagnostic Tests (This CR fully Rescinds and Replaces CR 7413)

I. SUMMARY OF CHANGES: This Change Request (CR) fully rescinds and replaces CR7413, Transmittal 2226, issued May 20, 2011, and revises the language in the background and policy section to clarify that Critical Access Hospitals are also included in this demonstration.

Section 3113 of the Affordable Care Act requires the Centers for Medicare and Medicaid Services (CMS) to conduct a demonstration project for certain complex diagnostic laboratory tests for a period of 2 years beginning January 1, 2012 or until the one hundred million dollars ($100,000,000) payment ceiling has been reached. This demonstration project will establish a separate payment method for these tests under which a clinical laboratory that would not normally receive direct payment from Medicare due to an "under arrangement" situation with a hospital will receive a direct payment from Medicare for performance of identified complex diagnostic laboratory tests.

The revision to the Pub 100-04, Claims Processing Manual, is an addition to Chapter 26, Section 10.4 that instructs providers and suppliers to enter Demonstration Project Identifier "56" on all Laboratory Affordable Care Act Section 3113 Demonstration claims, under Item 19.

EFFECTIVE DATE: For CWF/FISS: July 1, 2011 (Analysis, Design and Development) and January 1, 2012 (Additional Development, Testing and Implementation)
For MCS: July 1, 2011 (Analysis, Design, Development and Partial Implementation) and January 1, 2012 (Testing and Full Implementation)

IMPLEMENTATION DATE: January 3, 2012

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	26/10.4/Items 14-33 - Provider of Service or Supplier Information

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

Pub. 100-04	Transmittal: 2261	Date: July 29, 2011	Change Request: 7516

SUBJECT: Affordable Care Act – Section 3113 – Laboratory Demonstration for Certain Complex Diagnostic Tests (This CR Fully Rescinds and Replaces CR 7413)

Effective Date: For CWF/FISS: July 1, 2011 (Analysis, Design and Development) and January 1, 2012 (Additional Development, Testing and Implementation)

For MCS: July 1, 2011 (Analysis, Design, Development, and partial Implementation) and January 1, 2012 (Testing and Full Implementation)

Implementation Date: January 3, 2012

I. GENERAL INFORMATION

A. Background: Section 3113 of the Affordable Care Act requires the Secretary to conduct a demonstration under Part B, title XVIII of the Social Security Act (the Act) for 2 years subject to a $100 million total payment limit. This Demonstration will allow a separate payment to laboratories performing certain complex laboratory tests billed with a date of service that would, under standard Medicare rules (at 42 CFR. section 414.510(b)(2)(i)(A)), be bundled into the payment to the hospital or critical access hospital (CAH). Payment under the demonstration begins January 1, 2012. Once the demonstration has ended, payment for these tests will be made under the existing non-demonstration process.

Section 3113(a)(2) defines the term ‘‘complex diagnostic laboratory test’’ to mean a diagnostic laboratory test—(A) that is an analysis of gene protein expression, topographic genotyping, or a cancer chemotherapy sensitivity assay; (B) that is determined by the Secretary to be a laboratory test for which there is not an alternative test having equivalent performance characteristics; (C) which is billed using a Healthcare Common Procedure Coding System (HCPCS) code other than a not otherwise classified (NOC) code under such Coding System; (D) which is approved or cleared by the Food and Drug Administration or is covered under title XVIII of the Social Security Act; and (E) is described in section 1861(s)(3) of the Social Security Act (42 U.S.C. 1395x(s)(3)).

Section 3113(a)(3) defines separate payment as “direct payment to a laboratory (including a hospital-based or independent laboratory) that performs a complex diagnostic laboratory test with respect to a specimen collected from an individual during a period in which the individual is a patient of a hospital if the test is performed after such period of hospitalization and if separate payment would not otherwise be made under title XVIII of the Social Security Act [(the Act)] by reason of sections 1862(a)(14) and 1866(a)(1)(H)(i)” of the Act. In general terms, sections 1862(a)(14) and 1866(a)(1)(H) of the Act state that no Medicare payment will be made for non-physician services, such as diagnostic laboratory tests, furnished to a hospital or CAH patient unless the tests are furnished by the hospital or CAH, either directly or under arrangement. The date of service (DOS) rule at 42 CFR. section 414.510(b)(2)(i)(A) defines the date of service of a clinical laboratory test as the date the test was performed only if a test is ordered by the patient’s physician at least 14 days following the date of the patient’s discharge from the hospital. When a test is ordered by the patient’s physician less than 14 days following the date of the patient’s discharge from the hospital, the hospital or CAH must bill Medicare for a clinical laboratory test provided by a laboratory and the hospital or CAH would in turn pay the laboratory if the test was furnished under arrangement. Under the demonstration, a laboratory may bill Medicare directly for a complex clinical laboratory test which is ordered by the patient’s physician less than 14 days following the date of the patient’s discharge from the hospital or CAH.

This demonstration project shall be implemented in two phases. Phase I will occur during the July 2011 release and will consist of analysis, design, and coding. Phase II will be conducted during the January 2012 release and will consist of completion of any remaining coding, testing, and implementation. Note: MCS will only conduct testing during Phase II and all other programming activities will be conducted during Phase I.

B. Policy: All HCPCS codes included in this demonstration will be on the "Section 3113 Demonstration Fee Schedule" identified as data set, MU00.@BF12390.DEMO3113.V999999, (V999999 would correspond to the release date, e.g., a file released on January 1, 2012 would be V010112.) This fee schedule will be used to pay for HCPCS codes included in the demonstration and billed using the demonstration project identifier 56. Participation in this demonstration is voluntary and available to any laboratory nationwide. There will be no locality variation on the Section 3113 Demonstration Fee Schedule. All payments will be made under locality "DE" on the demonstration fee schedule. Changes to the 3113 demonstrations fee schedule, if any, will be made on a prospective basis, and will not be implemented retroactively. The "Test" Section 3113 Demonstration Fee Schedule is now available and identified under the dataset named MU00.@BF12390.DEMO3113.TEST.V010112. Future changes, if any, to this dataset will be communicated to contractors via a Technical Direction Letter (TDL).

CMS will provide the contractors the Section 3113 Demonstration Fee Schedule (also referred to or known as the Demonstration Test List) containing the payment amounts for the list of services to be covered by the demonstration. These payment amounts will be national amounts. (See Attachment C for the Section 3113 Demonstration Fee Schedule file layout). This file will contain the HCPCS code, a single national locality, and payment amount. This file will be updated quarterly on an as needed basis, via Change Request. HCPCS codes included in the demonstration project will be posted on the project website at: http://www.cms.gov/DemoProjectsEvalRpts/MD/itemdetail.asp?filterType=none&filterByDID=-99&sortByDID=3&sortOrder=descending&itemID=CMS1240611&intNumPerPage=10

Upon notification from CMS, contractors shall instruct their Enterprise Data Center (EDC)/data center to download from the Mainframe Telecommunications System via Connect: Direct and install the Section 3113 Demonstration Fee Schedule file. Contractors shall implement the Section 3113 Demonstration Fee Schedule effective January 1, 2012.

Congress has established a payment ceiling for this demonstration of one hundred million dollars ($100,000,000) for payments of identified complex laboratory tests or until the 2 years from the start of the demonstration has passed, whichever comes first.

For the purpose of this CR, the period of the 2 year demonstration period is effective for dates of service between January 1, 2012 and December 31, 2013.

Laboratories choosing to directly bill Medicare under the demonstration must submit a claim with a Project Identifier 56. By submitting a claim with the Section 3113 Demonstration Project Identifier "56," the laboratory agrees to cooperate with the independent evaluation and the implementation contractors. This may include providing data needed to assess the impact of the demonstration and participating in surveys and/or site visits as requested by these contractors.

Laboratories choosing to participate in this demonstration must bill the tests identified under the demonstration using the demonstration project identifier 56 in order to receive the special payment from the funding set aside for this demonstration. Once the one hundred million dollars ($100,000,000) payment ceiling has been reached in total payments with the demonstration project identifier 56 or 2 years has passed from the start of this demonstration, whichever comes first, claims using the demonstration project identifier 56 received after the applicable threshold has been reached will be rejected back to the laboratory.

Laboratories shall report the Demonstration Project Identifier 56 in item 19 on the CMS 1500 form, in locator 63 on the UB04, on the electronic claim in X12N 837P (HIPAA version) Loop 2300, REF02, REF01=P4 and in X12N 837I (HIPAA version) Loop 2300, REF02, G1 in REF01 DE 128. Claims billed for this demonstration cannot include non-demonstration services on the same claim/bill.

This CR also instructs the shared system maintainers to create a new Laboratory Demonstration 3113 Report by contractors and laboratories participating in this laboratory demonstration, daily volume and amount paid as well as cumulative volume and amount paid during the demonstration period. The Laboratory Demonstration 3113 Report by contractors and laboratories will report the aforementioned volumes and payments in total, and by individual demonstration HCPCS codes. This CR also provides specific instructions to the shared system maintainers and the EDC regarding the process for delivering Laboratory Demonstration 3113 Reports to CMS.

The shared system maintainers will generate daily reports for each contractor for use by CMS. These reports will be transmitted to the EDC. The EDC will transmit comma delimited files containing the report listed below via Connect: Direct for CMS retrieval:

- Laboratory Demonstration 3113 – Contractors Daily Report
- Data definitions
    - CCN: Claim Control Number of claim,
    - From Date of Service: Date reported in this field on each claim for each test,
    - To Date of Service: Date reported in this field on each claim for each test,
    - Procedure: Each test line procedure code with up to four modifiers,
    - NPI: National Provider Identifier for each test line,
    - Laboratory Name: Name of laboratory; truncate the name to use only 25 spaces.
    - CLIA Number: Clinical Laboratory Improvement Amendments certificate number for each test
    - Test (volume) numbers: the number of tests reported for each line item,
    - Daily Paid Amount: The paid amount for each test line,
    - Daily Total of Tests: Sum of all tests on a cumulative basis; for example, the first line of the daily report, if number of tests equals two (2), would be two (2), the second line of the report, if the number of tests reported is one (1), the cumulative total would be three (3), the third line of the report, if the number of services reported is three (3), then the cumulative total of tests would be six (6), etc.
    - Cumulative Paid Amount: Sum of all dollars paid on a cumulative basis, for example, the first line of the daily report, if amount paid is $100.00, the cumulative amount would be $100.00, the second line of the report, if amount paid is $100.00, the cumulative amount would be $200.00, the third line of the report, if the amount paid is $300.00, the cumulative amount would be $500.00, etc.
    - Cumulative Demo Total: This is a running sum of the amount paid for all claims processed by the contractor for the demonstration, beginning with the first claim on the first report. The total after a day or days of processing is carried over for use on the following days report.

The EDC will transmit the comma delimited files containing the Laboratory Demonstration 3113 reports for CMS retrieval via Connect: Direct on a daily basis.

The Laboratory Demonstration 3113 report files will be maintained in history within Connect: Direct indefinitely unless they are removed by CMS. EDC will transmit the Laboratory Demonstration report files to

the data set names determined by CMS. Changes to the data set name will be communicated to the EDC via a TDL.

The Common Working File maintainers shall also create a daily Laboratory Demonstration 3113 report based on sum of daily dollars paid and the sum of cumulative dollars during the demonstration period and send it via Connect: Direct for CMS retrieval on a daily basis:

- Laboratory Demonstration 3113 – CWF Daily Report
- Data definitions:
  - Date: Process Date reported in this field for each procedure code,
  - Procedure: Each test line procedure code without modifiers,
  - Daily Number of Tests: Daily sum of all tests per procedure code,
  - Daily Paid Amount: Daily sum of all dollars paid per procedure code,
  - Cumulative Demo Number of Tests: This is a running sum of all the tests processed per procedure code for the duration of the demonstration, and
  - Cumulative Demo Total: This is a running sum of the amount paid for all claims processed for the duration of the demonstration. The total after a day or days of processing is carried over for use on the following days report.

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	
7516-04.1	Contractors shall be aware that Demonstration Project Identifier 56 has been added to the Pub 100-04, Claims Processing Manual, Chapter 26, and Section 10.4. All other business requirements are located in Pub. 100-19 of this transmittal.	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	
7516-04.2	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 MLN Matters articles with localized information that would benefit their provider community in billing and administering the Medicare program correctly.	X		X	X						

IV. SUPPORTING INFORMATION

Section A: For any recommendations and supporting information associated with listed requirements, use the box below: N/A
Use "Should" to denote a recommendation.

X-Ref Requirement Number	Recommendations or other supporting information:

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

V. CONTACTS

Pre-Implementation Contact(s):
Linda Lebovic, (410) 786-3402 linda.lebovic@cms.hhs.gov (demonstration)

Wendy Knarr, (Dial relay at #711 then have agent dial (410) 786-0843) or Wendy.Knarr@cms.hhs.gov (carrier), Felicia Rowe (carrier) at (410) 786-5655 or Felicia.Rowe@cms.hhs.gov, and Fred Rooke (Fiscal Intermediary) at 404- 562-7205 or Fred.Rooke@cms.hhs.gov .

Post-Implementation Contact(s): Contact your Contracting Officer's Technical Representative (COTR) or Contractor Manager, as applicable.

VI. FUNDING

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

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

Section B: *For Medicare Administrative Contractors (MACs)*:

The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

10.4 - Items 14-33 - Provider of Service or Supplier Information

(Rev. 2261, Issued: 07-29-11, Effective: CWF/FISS: 07-01-11, (Analysis, Design and Development) and 01-01-12 (Additional Development, Testing and Implementation) For MCS: 07-01- 11 (Analysis, Design Development and Partial Implementation) and 01-01-12 (Testing and Full Implementation) Implementation: 01-03-12

Reminder: For date fields other than date of birth, all fields shall be one or the other format, 6-digit: (MM | DD | YY) or 8-digit: (MM | DD | CCYY). Intermixing the two formats on the claim is not allowed.

Item 14 - Enter either an 8-digit (MM | DD | CCYY) or 6-digit (MM | DD | YY) date of current illness, injury, or pregnancy. For chiropractic services, enter an 8-digit (MM | DD | CCYY) or 6-digit (MM | DD | YY) date of the initiation of the course of treatment and enter an 8-digit (MM | DD | CCYY) or 6-digit (MM | DD | YY) date in item 19.

Item 15 - Leave blank. Not required by Medicare.

Item 16 - If the patient is employed and is unable to work in his/her current occupation, enter an 8-digit (MM | DD | CCYY) or 6-digit (MM | DD | YY) date when patient is unable to work. An entry in this field may indicate employment related insurance coverage.

Item 17 - Enter the name of the referring or ordering physician if the service or item was ordered or referred by a physician. All physicians who order services or refer Medicare beneficiaries must report this data. When a claim involves multiple referring and/or ordering physicians, a separate Form CMS-1500 shall be used for each ordering/referring physician.

The term "physician" when used within the meaning of §1861(r) of the Act and used in connection with performing any function or action refers to:

1. A doctor of medicine or osteopathy legally authorized to practice medicine and surgery by the State in which he/she performs such function or action;

2. A doctor of dental surgery or dental medicine who is legally authorized to practice dentistry by the State in which he/she performs such functions and who is acting within the scope of his/her license when performing such functions;

3. A doctor of podiatric medicine for purposes of §§(k), (m), (p)(1), and (s) and §§1814(a), 1832(a)(2)(F)(ii), and 1835of the Act, but only with respect to functions which he/she is legally authorized to perform as such by the State in which he/she performs them;

4. A doctor of optometry, but only with respect to the provision of items or services described in §1861(s) of the Act which he/she is legally authorized to perform as a doctor of optometry by the State in which he/she performs them; or

5. A chiropractor who is licensed as such by a State (or in a State which does not license chiropractors as such), and is legally authorized to perform the services of a chiropractor in the jurisdiction in which he/she performs such services, and who meets uniform minimum standards specified by the Secretary, but only for purposes of §§1861(s)(1) and 1861(s)(2)(A) of the Act, and only with respect to treatment by means of manual manipulation of the spine (to correct a subluxation). For the purposes of §1862(a)(4) of the Act and subject to the limitations and conditions provided above, chiropractor includes a doctor of one of the arts specified in the statute and legally authorized to practice such art in the country in which the inpatient hospital services (referred to in §1862(a)(4) of the Act) are furnished.

Referring physician - is a physician who requests an item or service for the beneficiary for which payment may be made under the Medicare program.

Ordering physician - is a physician or, when appropriate, a non-physician practitioner who orders non-physician services for the patient. See Pub 100-02, Medicare Benefit Policy Manual, chapter 15 for non-physician practitioner rules. Examples of services that might be ordered include diagnostic laboratory tests, clinical laboratory tests, pharmaceutical services, durable medical equipment, and services incident to that physician's or non-physician practitioner's service.

The ordering/referring requirement became effective January 1, 1992, and is required by §1833(q) of the Act. **All claims** for Medicare covered services and items that are the result of a physician's order or referral shall include the ordering/referring physician's name. The following services/situations require the submission of the referring/ordering provider information:

- Medicare covered services and items that are the result of a physician's order or referral;
- Parenteral and enteral nutrition;
- Immunosuppressive drug claims;
- Hepatitis B claims;
- Diagnostic laboratory services;
- Diagnostic radiology services;
- Portable x-ray services;
- Consultative services;
- Durable medical equipment;

- When the ordering physician is also the performing physician (as often is the case with in-office clinical laboratory tests);

- When a service is incident to the service of a physician or non-physician practitioner, the name of the physician or non-physician practitioner who performs the initial service and orders the non-physician service must appear in item 17;

- When a physician extender or other limited licensed practitioner refers a patient for consultative service, submit the name of the physician who is supervising the limited licensed practitioner;

Item 17a – Leave blank.

Item 17b Form CMS-1500 – Enter the NPI of the referring/ordering physician listed in item 17. All physicians who order services or refer Medicare beneficiaries must report this data.

NOTE: Effective May 23, 2008, 17a is not to be reported but 17b MUST be reported when a service was ordered or referred by a physician.

Item 18 - Enter either an 8-digit (MM | DD | CCYY) or a 6-digit (MM | DD | YY) date when a medical service is furnished as a result of, or subsequent to, a related hospitalization.

Item 19 - Enter either a 6-digit (MM | DD | YY) or an 8-digit (MM | DD | CCYY) date patient was last seen and the NPI of his/her attending physician when a physician providing routine foot care submits claims.

For physical therapy, occupational therapy or speech-language pathology services, effective for claims with dates of service on or after June 6, 2005, the date last seen and the NPI of an ordering/referring/attending/certifying physician or non-physician practitioner is not required. If this information is submitted voluntarily, it must be correct or it will cause rejection or denial of the claim. However, when the therapy service is provided incident to the services of a physician or nonphysician practitioner, then incident to policies continue to apply. For example, for identification of the ordering physician who provided the initial service, see Item 17 and 17b, and for the identification of the supervisor, see item 24J of this section.

NOTE: Effective May 23, 2008, all identifiers submitted on the Form CMS-1500 MUST be in the form of an NPI.

Enter either a 6-digit (MM | DD | YY) or an 8-digit (MM | DD | CCYY) x-ray date for chiropractor services (if an x-ray, rather than a physical examination was the method used to demonstrate the subluxation). By entering an x-ray date and the initiation date for course of chiropractic treatment in item 14, the chiropractor is certifying that all the

relevant information requirements (including level of subluxation) of Pub. 100-02, Medicare Benefit Policy Manual, chapter 15, is on file, along with the appropriate x-ray and all are available for carrier review.

Enter the drug's name and dosage when submitting a claim for Not Otherwise Classified (NOC) drugs.

Enter a concise description of an "unlisted procedure code" or an NOC code if one can be given within the confines of this box. Otherwise an attachment shall be submitted with the claim.

Enter all applicable modifiers when modifier -99 (multiple modifiers) is entered in item 24d. If modifier -99 is entered on multiple line items of a single claim form, all applicable modifiers for each line item containing a -99 modifier should be listed as follows: 1=(mod), where the number 1 represents the line item and "mod" represents all modifiers applicable to the referenced line item.

Enter the statement "Homebound" when an independent laboratory renders an EKG tracing or obtains a specimen from a homebound or institutionalized patient. (See Pub. 100-02, Medicare Benefit Policy Manual, Chapter 15, "Covered Medical and Other Health Services," and Pub. 100-04, Medicare Claims Processing Manual, Chapter 16, "Laboratory Services From Independent Labs, Physicians and Providers," and Pub. 100-01, Medicare General Information, Eligibility, and Entitlement Manual, Chapter 5, "Definitions," respectively for the definition of "homebound" and a more complete definition of a medically necessary laboratory service to a homebound or an institutional patient.)

Enter the statement, "Patient refuses to assign benefits" when the beneficiary absolutely refuses to assign benefits to a non-participating physician/supplier who accepts assignment on a claim. In this case, payment can only be made directly to the beneficiary.

Enter the statement, "Testing for hearing aid" when billing services involving the testing of a hearing aid(s) is used to obtain intentional denials when other payers are involved.

When dental examinations are billed, enter the specific surgery for which the exam is being performed.

Enter the specific name and dosage amount when low osmolar contrast material is billed, but only if HCPCS codes do not cover them.

Enter a 6-digit (MM | DD | YY) or an 8-digit (MM | DD | CCYY) assumed and/or relinquished date for a global surgery claim when providers share post-operative care.

Enter demonstration ID number "30" for all national emphysema treatment trial claims.

Enter demonstration ID number "56" for all national Laboratory Affordable Care Act Section 3113 Demonstration claims.

Enter the NPI of the physician who is performing the technical or professional component of a diagnostic test that is subject to the anti-markup payment limitation. (See Pub. 100-04, chapter 1, section 30.2.9 for additional information.)

NOTE: Effective May 23, 2008, all identifiers submitted on the Form CMS-1500 MUST be in the form of an NPI.

Method II suppliers shall enter the most current HCT value for the injection of Aranesp for ESRD beneficiaries on dialysis. (See Pub. 100-04, chapter 8, section 60.7.2.)

Individuals and entities who bill carriers or A/B MACs for administrations of ESAs or Part B anti-anemia drugs not self-administered (other than ESAs) in the treatment of cancer must enter the most current hemoglobin or hematocrit test results. The test results shall be entered as follows: TR= test results (backslash), R1=hemoglobin, or R2=hematocrit (backslash), and the most current numeric test result figure up to 3 numerics and a decimal point [xx.x]). Example for hemoglobin tests: TR/R1/9.0, Example for Hematocrit tests: TR/R2/27.0.

Item 20 - Complete this item when billing for diagnostic tests subject to the anti-markup payment limitation. Enter the acquisition price under charges if the "yes" block is checked. A "yes" check indicates that an entity other than the entity billing for the service performed the diagnostic test. A "no" check indicates "no anti-markup tests are included on the claim." When "yes" is annotated, item 32 shall be completed. When billing for multiple anti-markup tests, each test shall be submitted on a separate claim Form CMS-1500. Multiple anti-markup tests may be submitted on the ASC X12 837 electronic format as long as appropriate line level information is submitted when services are rendered at different service facility locations. See chapter 1.

NOTE: This is a required field when billing for diagnostic tests subject to the anti-markup payment limitation.

Item 21 - Enter the patient's diagnosis/condition. With the exception of claims submitted by ambulance suppliers (specialty type 59), all physician and nonphysician specialties (i.e., PA, NP, CNS, CRNA) use an ICD-9-CM code number and code to the highest level of specificity for the date of service. Enter up to four diagnoses in priority order. All narrative diagnoses for nonphysician specialties shall be submitted on an attachment.

Item 22 - Leave blank. Not required by Medicare.

Item 23 - Enter the Quality Improvement Organization (QIO) prior authorization number for those procedures requiring QIO prior approval.

Enter the Investigational Device Exemption (IDE) number when an investigational device is used in an FDA-approved clinical trial. Post Market Approval number should also be placed here when applicable.

For physicians performing care plan oversight services, enter the NPI of the home health agency (HHA) or hospice when CPT code G0181 (HH) or G0182 (Hospice) is billed.

Enter the 10-digit Clinical Laboratory Improvement Act (CLIA) certification number for laboratory services billed by an entity performing CLIA covered procedures.

For ambulance claims, enter the ZIP code of the loaded ambulance trip's point-of-pickup.

NOTE: Item 23 can contain only one condition. Any additional conditions should be reported on a separate Form CMS-1500.

Item 24 - The six service lines in section 24 have been divided horizontally to accommodate submission of supplemental information to support the billed service. The top portion in each of the six service lines is shaded and is the location for reporting supplemental information. It is not intended to allow the billing of 12 service lines.

When required to submit NDC drug and quantity information for Medicaid rebates, submit the NDC code in the red shaded portion of the detail line item in positions 01 through position 13. The NDC is to be preceded with the qualifier N4 and followed immediately by the 11 digit NDC code (e.g. N499999999999). Report the NDC quantity in positions 17 through 24 of the same red shaded portion. The quantity is to be preceded by the appropriate qualifier: UN (units), F2 (international units), GR (gram) or ML (milliliter). There are six bytes available for quantity. If the quantity is less than six bytes, left justify and space-fill the remaining positions (e.g. UN2 or F2999999).

Item 24A - Enter a 6-digit or 8-digit (MMDDCCYY) date for each procedure, service, or supply. When "from" and "to" dates are shown for a series of identical services, enter the number of days or units in column G. This is a required field. Return as unprocessable if a date of service extends more than 1 day and a valid "to" date is not present.

Item 24B - Enter the appropriate place of service code(s) from the list provided in section 10.5. Identify the location, using a place of service code, for each item used or service performed. This is a required field.

NOTE: When a service is rendered to a hospital inpatient, use the "inpatient hospital" code.

Item 24C - Medicare providers are not required to complete this item.

Item 24D - Enter the procedures, services, or supplies using the CMS Healthcare Common Procedure Coding System (HCPCS) code. When applicable, show HCPCS

code modifiers with the HCPCS code. The Form CMS-1500 has the ability to capture up to four modifiers.

Enter the specific procedure code without a narrative description. However, when reporting an "unlisted procedure code" or a "not otherwise classified" (NOC) code, include a narrative description in item 19 if a coherent description can be given within the confines of that box. Otherwise, an attachment shall be submitted with the claim. This is a required field.

Return as unprocessable if an "unlisted procedure code" or an (NOC) code is indicated in item 24d, but an accompanying narrative is not present in item 19 or on an attachment.

Item 24E - Enter the diagnosis code reference number as shown in item 21 to relate the date of service and the procedures performed to the primary diagnosis. Enter only one reference number per line item. When multiple services are performed, enter the primary reference number for each service, either a 1, or a 2, or a 3, or a 4. This is a required field.

If a situation arises where two or more diagnoses are required for a procedure code (e.g., pap smears), the provider shall reference only one of the diagnoses in item 21.

Item 24F- Enter the charge for each listed service.

Item 24G - Enter the number of days or units. This field is most commonly used for multiple visits, units of supplies, anesthesia minutes, or oxygen volume. If only one service is performed, the numeral 1 must be entered.

Some services require that the actual number or quantity billed be clearly indicated on the claim form (e.g., multiple ostomy or urinary supplies, medication dosages, or allergy testing procedures). When multiple services are provided, enter the actual number provided.

For anesthesia, show the elapsed time (minutes) in item 24g. Convert hours into minutes and enter the total minutes required for this procedure.

For instructions on submitting units for oxygen claims, see chapter 20, section 130.6 of this manual.

Beginning with dates of service on and after January 1, 2011, for ambulance mileage, enter the number of loaded miles traveled rounded up to the nearest tenth of a mile up to 100 miles. For mileage totaling 100 miles and greater, enter the number of covered miles rounded up to the nearest whole number miles. If the total mileage is less than 1 whole mile, enter a “0” before the decimal (e.g. 0.9). See Pub. 100-04, chapter 15, §20.2 for more information on loaded mileage and §30.1.2 for more information on reporting fractional mileage.

NOTE: This field should contain an appropriate numerical value. The B/MAC should program their system to automatically default "1" unit when the information in this field is missing to avoid returning as unprocessable, except on claims for ambulance mileage. For ambulance mileage claims, contractors shall automatically default "0.1" unit when total mileage units are missing in this field.

Item 24H - Leave blank. Not required by Medicare.

Item 24I - Enter the ID qualifier 1C in the shaded portion.

Item 24J - Enter the rendering provider's NPI number in the lower unshaded portion. In the case of a service provided incident to the service of a physician or non-physician practitioner, when the person who ordered the service is not supervising, enter the NPI of the supervisor in the lower unshaded portion.

This unprocessable instruction does not apply to influenza virus and pneumococcal vaccine claims submitted on roster bills as they do not require a rendering provider NPI.

NOTE: Effective May 23, 2008, the shaded portion of 24J is not to be reported.

Item 25 - Enter the provider of service or supplier Federal Tax ID (Employer Identification Number or Social Security Number) and check the appropriate check box. Medicare providers are not required to complete this item for crossover purposes since the Medicare contractor will retrieve the tax identification information from their internal provider file for inclusion on the COB outbound claim. However, tax identification information is used in the determination of accurate National Provider Identifier reimbursement. Reimbursement of claims submitted without tax identification information will/may be delayed.

Item 26 - Enter the patient's account number assigned by the provider's of service or supplier's accounting system. This field is optional to assist the provider in patient identification. As a service, any account numbers entered here will be returned to the provider.

Item 27 - Check the appropriate block to indicate whether the provider of service or supplier accepts assignment of Medicare benefits. If Medigap is indicated in item 9 and Medigap payment authorization is given in item 13, the provider of service or supplier shall also be a Medicare participating provider of service or supplier and accept assignment of Medicare benefits for all covered charges for all patients.

The following providers of service/suppliers and claims can only be paid on an assignment basis:

- Clinical diagnostic laboratory services;

- Physician services to individuals dually entitled to Medicare and Medicaid;

- Participating physician/supplier services;

- Services of physician assistants, nurse practitioners, clinical nurse specialists, nurse midwives, certified registered nurse anesthetists, clinical psychologists, and clinical social workers;

- Ambulatory surgical center services for covered ASC procedures;

- Home dialysis supplies and equipment paid under Method II;

- Ambulance services;

- Drugs and biologicals; and

- Simplified Billing Roster for influenza virus vaccine and pneumococcal vaccine.

Item 28 - Enter total charges for the services (i.e., total of all charges in item 24f).

Item 29 - Enter the total amount the patient paid on the covered services only.

Item 30 - Leave blank. Not required by Medicare.

Item 31 - Enter the signature of provider of service or supplier, or his/her representative, and either the 6-digit date (MM | DD | YY), 8-digit date (MM | DD | CCYY), or alpha-numeric date (e.g., January 1, 1998) the form was signed.

In the case of a service that is provided incident to the service of a physician or non-physician practitioner, when the ordering physician or non-physician practitioner is directly supervising the service as in 42 CFR 410.32, the signature of the ordering physician or non-physician practitioner shall be entered in item 31. When the ordering physician or non-physician practitioner is not supervising the service, then enter the signature of the physician or non-physician practitioner providing the direct supervision in item 31.

NOTE: This is a required field, however the claim can be processed if the following is true. If a physician, supplier, or authorized person's signature is missing, but the signature is on file; or if any authorization is attached to the claim or if the signature field has "Signature on File" and/or a computer generated signature.

Item 32 - Enter the name and address, and ZIP code of the facility if the services were furnished in a hospital, clinic, laboratory, or facility other than the patient's home or physician's office. Effective for claims received on or after April 1, 2004, enter the name, address, and ZIP code of the service location for all services other than those furnished in place of service home – 12. Effective for claims received on or after April 1, 2004, on

the Form CMS-1500, only one name, address and ZIP code may be entered in the block. If additional entries are needed, separate claim forms shall be submitted.

Effective January 1, 2011, for claims processed on or after January 1, 2011, submission of the location where the service was rendered will be required for all POS codes.

Providers of service (namely physicians) shall identify the supplier's name, address, and ZIP code when billing for anti-markup tests. When more than one supplier is used, a separate Form CMS-1500 shall be used to bill for each supplier. (See Pub. 100-04, chapter 1, §10.1.1.2 for more information on payment jurisdiction for claims subject to the anti-markup limitation.)

For foreign claims, only the enrollee can file for Part B benefits rendered outside of the United States. These claims will not include a valid ZIP code. When a claim is received for these services on a beneficiary submitted Form CMS-1490S, before the claim is entered in the system, it should be determined if it is a foreign claim. If it is a foreign claim, follow instructions in chapter 1 for disposition of the claim. The carrier processing the foreign claim will have to make necessary accommodations to verify that the claim is not returned as unprocessable due to the lack of a ZIP code.

For durable medical, orthotic, and prosthetic claims, the name and address of the location where the order was accepted must be entered (DME MAC only). This field is required. When more than one supplier is used, a separate Form CMS-1500 shall be used to bill for each supplier. This item is completed whether the supplier's personnel performs the work at the physician's office or at another location.

If the supplier is a certified mammography screening center, enter the 6-digit FDA approved certification number.

Complete this item for all laboratory work performed outside a physician's office. If an independent laboratory is billing, enter the place where the test was performed.

Item 32a - If required by Medicare claims processing policy, enter the NPI of the service facility.

Item 32b - Effective May 23, 2008, Item 32b is not to be reported.

Item 33 - Enter the provider of service/supplier's billing name, address, ZIP code, and telephone number. This is a required field.

Item 33a - Enter the NPI of the billing provider or group. This is a required field.

Item 33b - Effective May 23, 2008, Item 33b is not to be reported.