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|----------------------------------|---|
| <b>CMS Manual System</b>         | <b>Department of Health &amp; Human Services (DHHS)</b>   |
| <b>Pub 100-19 Demonstrations</b> | <b>Centers for Medicare &amp; Medicaid Services (CMS)</b> |
| <b>Transmittal 78</b>            | <b>Date: JULY 29, 2011</b>                                |
|                                  | <b>Change Request 7516</b>                                |

**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 CR 7413, Transmittal 74, issued July 15, 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.

**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

|              |   |
|--------------|---|
| <b>R/N/D</b> | <b>CHAPTER / SECTION / SUBSECTION / TITLE</b> |
| <b>N/A</b>   |   |

### **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**

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

# Attachment – Business Requirement

|             |                 |                     |                      |
|-------------|-----------------|---------------------|----------------------|
| Pub. 100-19 | Transmittal: 78 | Date: July 29, 2011 | Change Request: 7516 |
|-------------|-----------------|---------------------|----------------------|

**SUBJECT: Affordable Care Act – Section 3113 – Laboratory Demonstration for Certain Complex Diagnostic Tests (This Change Request (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 demonstration 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.

See Attachment A for the Laboratory Demonstration 3113 Report File Layout for Contractors and EDC.  
 See Attachment B for the Laboratory Demonstration 3113 Report File Layout for CWF.  
 See Attachment C for the Section 3113 Demonstration Fee Schedule Record Layout File.

## 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   | D<br>M<br>E | 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 |             |             |             | OTH<br>ER |
|                |  |   |             |        |                                 |                  | F<br>I<br>S<br>S          | M<br>C<br>S | V<br>M<br>S | C<br>W<br>F |           |
| 7516-19.1      | Contractors shall pay a claim (For Part A contractors only allow Type of Bill 14X on UB-04) submitted with the demonstration project identifier 56 and all line items have a valid HCPCS code on the Section 3113 Demonstration Fee Schedule with DOS effective between January 1, 2012 and December 31, 2013 or until the one hundred million dollars (\$100,000,000) payment ceiling has been reached. | X   |             | X      | X                               |                  | X                         | X           |             |             |           |
| 7516 -19.1.1   | CWF System Maintainers shall create an edit to reject a claim submitted with the demonstration project identifier 56 and DOS prior to January 1, 2012.   |   |             |        |                                 |                  |                           |             |             |             | X         |
| 7516 -19.1.1.1 | CWF System Maintainers shall reject and the contractors shall reject/return as unprocessable a claim submitted with the demonstration project identifier 56 and DOS prior to January 1, 2012.  | X   |             | X      | X                               |                  | X                         |             |             |             | X         |
| 7516 -19.1.1.2 | Contractors shall use Group Code "CO" with the messages below when rejecting/returning as unprocessable a claim submitted with the demonstration project identifier 56 and DOS prior to January 1, 2012:   | X   |             | X      | X                               |                  |                           |             |             |             |           |

| Number     | Requirement  | Responsibility (place an "X" in each applicable column) |             |        |                                 |                  |                           |             |             |             |           |
|------------|--|---|-------------|--------|---------------------------------|------------------|---------------------------|-------------|-------------|-------------|-----------|
|            |  | A<br>/<br>B   | D<br>M<br>E | F<br>I | C<br>A<br>R<br>R<br>I<br>E<br>R | R<br>H<br>R<br>I | Shared-System Maintainers |             |             |             | OTH<br>ER |
|            |  |   |             |        |                                 |                  | F<br>I<br>S<br>S          | M<br>C<br>S | V<br>M<br>S | C<br>W<br>F |           |
|            | <p>Reason code 96 – Non-covered charge(s). At least one Remark Code must be provided (may be comprised of either the NCPDP Reject Reason Code, or Remittance Advice Remark Code that is not an ALERT.) Note: Refer to the 835 Healthcare Policy Identification Segment (loop 2110 Service Payment Information REF), if present.</p> <p>Remark code: M114 - This service was processed in accordance with rules and guidelines under the DMEPOS Competitive Bidding Program or a Demonstration Project. For more information regarding these projects, contact your local contractor.</p> <p>Remark code: N83 - No appeal rights. Adjudicative decision based on the provisions of a demonstration project.</p>   |   |             |        |                                 |                  |                           |             |             |             |           |
| 7516 -19.2 | <p>Contractors shall reject/return as unprocessable a claim submitted with the demonstration project identifier 56 if any line item on the claim is not a valid HCPCS code on the Section 3113 Demonstration Fee Schedule with DOS effective between January 1, 2012 and December 31, 2013, or until the one hundred million dollars (\$100,000,000) payment ceiling has been reached and use all of the following messages (Group code: CO):</p> <p>Reason code 96 – Non-covered charge(s). At least one Remark Code must be provided (may be comprised of either the NCPDP Reject Reason Code, or Remittance Advice Remark Code that is not an ALERT.) Note: Refer to the 835 Healthcare Policy Identification Segment (loop 2110 Service Payment Information REF), if present.</p> <p>Remark code: M114 - This service was processed in accordance with rules and guidelines under the DMEPOS Competitive Bidding Program or a Demonstration Project. For more information regarding these projects, contact your local contractor.</p> <p>Remark code: N83 - No appeal rights. Adjudicative decision based on the provisions of a demonstration project.</p> | X   |             | X      | X                               |                  | X                         |             |             |             |           |





| Number       | Requirement   | Responsibility (place an "X" in each applicable column) |             |        |                                 |                       |                           |             |             |             |           |
|--------------|---|---|-------------|--------|---------------------------------|-----------------------|---------------------------|-------------|-------------|-------------|-----------|
|              |   | A<br>/<br>B   | D<br>M<br>E | F<br>I | C<br>A<br>R<br>R<br>I<br>E<br>R | R<br>A<br>H<br>R<br>I | Shared-System Maintainers |             |             |             | OTH<br>ER |
|              |   |   |             |        |                                 |                       | F<br>I<br>S<br>S          | M<br>C<br>S | V<br>M<br>S | C<br>W<br>F |           |
| 7516 -19.5   | CWF system maintainers shall allow Section 3113 Demonstration Project Identifier 56 in CWF.   |   |             |        |                                 |                       |                           |             |             |             | X         |
| 7516 -19.6   | CWF System Maintainers shall create an edit to reject a claim submitted with the demonstration project identifier 56, for DOS between January 1, 2012 – December 31, 2013, or until the 100,000,000 payment ceiling has been reached, if the DOS is greater than 14 days following the date of the patient’s discharge from a covered hospital or CAH encounter (whether inpatient type of bill 11X and 12X or outpatient type of bill 13X and 85X).  |   |             |        |                                 |                       |                           |             |             |             | X         |
| 7516 -19.6.1 | CWF System Maintainers shall reject and the contractors shall reject/return as unprocessable a claim submitted with the demonstration project identifier 56, between January 1, 2012 – December 31, 2013, or until the 100,000,000 payment ceiling has been reached, if the DOS is greater than 14 days following the date of the patient’s discharge from a covered hospital or CAH encounter (whether inpatient type of bill -11X and -12X or outpatient type of bill -13X and -85X).   | X   |             | X      | X                               |                       | X                         |             |             |             | X         |
| 7516 -19.6.2 | Contractors shall use Group Code “CO” with the messages below when rejecting/returning as unprocessable a claim submitted with the demonstration project identifier 56, between January 1, 2012 – December 31, 2013, or until the 100,000,000 payment ceiling has been reached, if the DOS is greater than 14 days following the date of the patient’s discharge from a covered hospital or CAH encounter (whether inpatient type of bill -11X and -12X or outpatient type of bill -13X and -85X):<br><br>Reason code 96 – Non-covered charge(s). At least one Remark Code must be provided (may be comprised of either the NCPDP Reject Reason Code, or Remittance Advice Remark Code that is not an ALERT.) Note: Refer to the 835 Healthcare Policy Identification Segment (loop 2110 Service Payment Information REF), if present.<br><br>Remark code: M114 - This service was processed in accordance with rules and guidelines under the DMEPOS Competitive Bidding Program or a Demonstration Project. For more information regarding these projects, contact your local contractor. | X   |             | X      | X                               |                       |                           |             |             |             |           |

| Number       | Requirement  | Responsibility (place an "X" in each applicable column) |             |        |                                 |                       |                           |             |             |             |           |
|--------------|--|---|-------------|--------|---------------------------------|-----------------------|---------------------------|-------------|-------------|-------------|-----------|
|              |  | A<br>/<br>B   | D<br>M<br>E | F<br>I | C<br>A<br>R<br>R<br>I<br>E<br>R | R<br>A<br>H<br>R<br>I | Shared-System Maintainers |             |             |             | OTH<br>ER |
|              |  |   |             |        |                                 |                       | F<br>I<br>S<br>S          | M<br>C<br>S | V<br>M<br>S | C<br>W<br>F |           |
|              | Remark code: N83 - No appeal rights. Adjudicative decision based on the provisions of a demonstration project.   |   |             |        |                                 |                       |                           |             |             |             |           |
| 7516 -19.7   | CWF shall create an edit to reject any claims with a demonstration project identifier 56 once the one hundred million dollars (\$100,000,000) payment ceiling has been met or for dates of service on or after January 1, 2014, whichever comes first.   |   |             |        |                                 |                       |                           |             |             |             | X         |
| 7516 -19.7.1 | CWF shall reject any claims with a demonstration project identifier 56 once the one hundred million dollars (\$100,000,000) payment ceiling has been met or for dates of service on or after January 1, 2014, whichever comes first.   |   |             |        |                                 |                       |                           |             |             |             | X         |
| 7516 -19.7.2 | Upon receipt of CWF reject, contractors shall reject/return as unprocessable any claims with the demonstration project identifier 56 after the one hundred million dollars (\$100,000,000) payment ceiling has been met or for dates of service on or after January 1, 2014, whichever comes first, and shall use Group code: CO with all of the following messages:<br><br>Reason code 96 – Non-covered charge(s). At least one Remark Code must be provided (may be comprised of either the NCPDP Reject Reason Code, or Remittance Advice Remark Code that is not an ALERT.) Note: Refer to the 835 Healthcare Policy Identification Segment (loop 2110 Service Payment Information REF), if present.<br><br>Remark Code: M116 – Processed under a demonstration project or program. Project or program is ending and additional services may not be paid under this project or program<br><br>Remark code: N83 - No appeal rights. Adjudicative decision based on the provisions of a demonstration project. | X   |             | X      | X                               |                       | X                         |             |             |             |           |
| 7516 -19.8   | The shared system maintainers shall create a new daily report for each contractor of claims paid under laboratory Demonstration 3113 project.  |   |             |        |                                 |                       | X                         | X           |             |             |           |
| 7516 -19.8.1 | All data on the new report shall be from adjudicated claims.   |   |             |        |                                 |                       | X                         | X           |             |             |           |
| 7516 -19.8.2 | The shared system maintainers shall produce these reports in comma delimited file format by using the  |   |             |        |                                 |                       | X                         | X           |             |             |           |

| Number       | Requirement   | Responsibility (place an "X" in each applicable column) |             |        |                                 |             |                           |             |             |             |           |
|--------------|---|---|-------------|--------|---------------------------------|-------------|---------------------------|-------------|-------------|-------------|-----------|
|              |   | A<br>/<br>B   | D<br>M<br>E | F<br>I | C<br>A<br>R<br>R<br>I<br>E<br>R | R<br>H<br>I | Shared-System Maintainers |             |             |             | OTH<br>ER |
|              |   |   |             |        |                                 |             | F<br>I<br>S<br>S          | M<br>C<br>S | V<br>M<br>S | C<br>W<br>F |           |
|              | data elements specified in Attachment A.  |   |             |        |                                 |             |                           |             |             |             |           |
| 7516 -19.8.3 | <p>The shared system maintainer shall title these reports as follows:</p> <ul style="list-style-type: none"> <li>“Laboratory Demonstration – Daily Laboratory Demonstration 3113”</li> </ul>  |   |             |        |                                 |             | X                         | X           |             |             |           |
| 7516 -19.9   | <p>The EDC shall send the daily Laboratory Demonstration 3113 reports for deliverance via Connect: Direct on a daily basis for CMS retrieval under the following data set name:</p> <p>Production:<br/>P#EFT.ON.SEC3113.DEM.CXXXXX.DYYMMD<br/>D.THHMMSS</p> <p>Testing:<br/>T#EFT.ON.SEC3113.DEM.CXXXXX.DYYMMD<br/>D.THHMMSST</p> |   |             |        |                                 |             |                           |             |             | EDC         |           |
| 7516 -19.10  | Contractors shall receive notice via a TDL in the event the data set name listed in BR 7516-19.3.1, 7516-19.4.1, and 7516-19.9 has been changed for any reason.   | X   |             | X      | X                               |             |                           |             |             |             | EDC       |
| 7516 -19.11  | Contractors shall receive notice via a TDL when the one hundred million dollars (\$100,000,000) payment ceiling is close to being met and another TDL when the payment ceiling has been met.  | 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<br><br><br><br> | C<br>A<br>R<br>R<br>I<br>E<br>R | R<br>H<br>R<br>I<br><br><br> | Shared-System Maintainers |             |             |  | OTH<br>ER |
|             |   |   |                                |                        |                                 | F<br>I<br>S<br>S             | M<br>C<br>S               | V<br>M<br>S | C<br>W<br>F |  |           |
| 7516 -19.12 | <p>A provider education article related to this instruction will be available at <a href="http://www.cms.hhs.gov/MLNMattersArticles/">http://www.cms.hhs.gov/MLNMattersArticles/</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.</p> <p>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                               |                              |                           |             |             |  |           |

### IV. SUPPORTING INFORMATION

**Section A: For any recommendations and supporting information associated with listed requirements, use the box below:**

*Use "Should" to denote a recommendation.*

| X-Ref Requirement Number      | Recommendations or other supporting information:  |
|-------------------------------|---|
| CR 7516.19.3.3<br>Pub. 100-19 | Announcements/Updates in regards to the demonstration will be made via the project listserv at: <a href="https://list.nih.gov/cgi-bin/wa.exe?SUBED1=MEDICARE_LAB_DEMO&amp;A=1">https://list.nih.gov/cgi-bin/wa.exe?SUBED1=MEDICARE_LAB_DEMO&amp;A=1</a> |

**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](mailto: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](mailto:Wendy.Knarr@cms.hhs.gov) (carrier), Felicia Rowe at 410-786-5655 or [Felicia.rowe@cms.hhs.gov](mailto:Felicia.rowe@cms.hhs.gov) and Fred Rooke (Fiscal Intermediary) at 404- 562-7205 or [Fred.Rooke@cms.hhs.gov](mailto: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.

**3 Attachments**

CONTRACTOR NUMBER: 99999

CONTRACTORS NAME  
LABORATORY DEMONSTRATION PROJECT  
DAILY LABORATORY DEMONSTRATION  
3113 REPORT

CYCLE DATE: N/A  
RUN DATE: MM/DD/YYYY  
RUN TIME: HH:MM:SS  
PAGE: 1

REPORT NUMBER: 111

| CCN           | FROM DATE<br>OF SERVICE | TO DATE<br>OF SERVICE | PROCEDURE    | NPI        | LABORATORY NAME | CLIA<br>NUMBER | SERVICE<br>VOLUME<br>NUMBERS | DAILY<br>PAID<br>AMOUNT | CUMULATIVE<br>DAILY TOTAL<br>TESTS | CUMULATIVE<br>PAID<br>AMOUNT | CUMULATIVE<br>DEMO TOTAL |
|---------------|-------------------------|-----------------------|--------------|------------|-----------------|----------------|------------------------------|-------------------------|------------------------------------|------------------------------|--------------------------|
| 1111111111100 | 01/22/2011              | 01/22/2011            | A2222AABCCDD | 1111111111 | ABC LABORATORY  | XXDXXXXXXX     | XXX,XXX                      | XXX,XXX,XX              | XXX,XXX,XX                         | XXX,XXX,XX                   | XXX,XXX,XX               |
|               | 02/22/2011              | 02/22/2011            | A1111AABCCDD | 1111111111 | ABC LABORATORY  | XXDXXXXXXX     | XXX,XXX                      | XXX,XXX,XX              | XXX,XXX,XX                         | XXX,XXX,XX                   | XXX,XXX,XX               |
| 2222222222000 | 02/02/2011              | 02/02/2011            | A3333AABCCDD | 3333333333 | DFG LABORATORY  | XXDXXXXXXX     | XXX,XXX                      | XXX,XXX,XX              | XXX,XXX,XX                         | XXX,XXX,XX                   | XXX,XXX,XX               |
| 3333333333000 | 02/28/2011              | 02/28/2011            | A2222AABCCDD | 1111111111 | ABC LABORATORY  | XXDXXXXXXX     | XXX,XXX                      | XXX,XXX,XX              | XXX,XXX,XX                         | XXX,XXX,XX                   | XXX,XXX,XX               |

CWF  
LABORATORY DEMONSTRATION PROJECT  
DAILY LABORATORY DEMONSTRATION  
3113 REPORT

CYCLE DATE: N/A  
RUN DATE: MM/DD/YYYY  
RUN TIME: HH:MM:SS  
PAGE: 1

REPORT NUMBER: 111  
START DEMO DATE: MMDDYYYY  
STOP DEMO DATE: MMDDYYYY

| DATE:             | PROCEDURE:     | DAILY NUMBER<br>OF TESTS | DAILY PAID<br>AMOUNT | CUMULATIVE DEMO<br>NUMBER OF TESTS | CUMULATIVE<br>DEMO TOTAL |
|-------------------|----------------|--------------------------|----------------------|------------------------------------|--------------------------|
| -----<br>MMDDYYYY | -----<br>A2222 | -----<br>XXX,XXX         | -----<br>XXX,XXX,XX  | -----<br>XXX,XXX                   | -----<br>XXX,XXX,XX      |

SAMPLE

## SECTION 3113 DEMONSTRATION FEE SCHEDULE PAYMENT AMOUNT FILE

Contents: This file contains Clinical Lab fee schedule payment amounts for services covered by the Affordable Care Act Section 3113.

File Organization: This file contains one record for each unique HCPCS code.

Data Set Name: For files provided to the claims processing contractor, recommend the following naming convention:  
[MU00.@BF12394.3113DEMO.V999999](#) (V999999 would correspond to the release data, i.e. V010111).

### SECTION 3113 DEMONSTRATION FEE SCHEDULE PAYMENT AMOUNT FILE LAYOUT

| <u>DATA ELEMENT</u> | <u>LOCATION</u> | <u>COBOL PIC</u> | <u>DESCRIPTION</u>                                |
|---------------------|-----------------|------------------|---|
| DATA RECORD         |                 |                  |   |
| HCPCS Code          | 1-5             | x(5)             | CPT or Level 2 HCPCS code number for the service. |
| Locality            | 6-7             | x(2)             | Value for Locality will be "DE"                   |
| Payment Amount      | 8-17            | 9(7).99          | Pricing amount set by ORD.                        |



CONTRACTOR NUMBER: 99999

REPORT NUMBER: 111

CONTRACTORS NAME  
LABORATORY DEMONSTRATION PROJECT  
DAILY LABORATORY DEMONSTRATION  
3113 REPORT

CYCLE DATE: N/A  
RUN DATE: MM/DD/YYYY  
RUN TIME: HH:MM:SS  
PAGE: 1

| CCN           | FROM DATE<br>OF SERVICE | TO DATE<br>OF SERVICE | PROCEDURE     | NPI        | LABORATORY NAME | CLIA<br>NUMBER | SERVICE<br>VOLUME<br>NUMBERS | DAILY<br>PAID<br>AMOUNT | CUMULATIVE<br>DAILY TOTAL<br>TESTS | CUMULATIVE<br>PAID<br>AMOUNT | CUMULATIVE<br>DEMO TOTAL |
|---------------|-------------------------|-----------------------|---------------|------------|-----------------|----------------|------------------------------|-------------------------|------------------------------------|------------------------------|--------------------------|
| 111111111100  | 01/22/2011              | 01/22/2011            | A2222AABBCCDD | 1111111111 | ABC LABORATORY  | XXDXXXXXXX     | XXX,XXX                      | XXX,XXX,XX              | XXX,XXX,XX                         | XXX,XXX,XX                   | XXX,XXX,XX               |
|               | 02/22/2011              | 02/22/2011            | A1111AABBCCDD | 1111111111 | ABC LABORATORY  | XXDXXXXXXX     | XXX,XXX                      | XXX,XXX,XX              | XXX,XXX,XX                         | XXX,XXX,XX                   | XXX,XXX,XX               |
| 2222222222000 | 02/02/2011              | 02/02/2011            | A3333AABBCCDD | 3333333333 | DFG LABORATORY  | XXDXXXXXXX     | XXX,XXX                      | XXX,XXX,XX              | XXX,XXX,XX                         | XXX,XXX,XX                   | XXX,XXX,XX               |
| 3333333333000 | 02/28/2011              | 02/28/2011            | A2222AABBCCDD | 1111111111 | ABC LABORATORY  | XXDXXXXXXX     | XXX,XXX                      | XXX,XXX,XX              | XXX,XXX,XX                         | XXX,XXX,XX                   | XXX,XXX,XX               |

SAMPLE

REPORT NUMBER: 111  
START DEMO DATE: MMDDYYYY  
STOP DEMO DATE: MMDDYYYY

CWF  
LABORATORY DEMONSTRATION PROJECT  
DAILY LABORATORY DEMONSTRATION  
3113 REPORT

CYCLE DATE: N/A  
RUN DATE: MM/DD/YYYY  
RUN TIME: HH:MM:SS  
PAGE: 1

| DATE:             | PROCEDURE:     | DAILY NUMBER<br>OF TESTS | DAILY PAID<br>AMOUNT | CUMULATIVE DEMO<br>NUMBER OF TESTS | CUMULATIVE<br>DEMO TOTAL |
|-------------------|----------------|--------------------------|----------------------|------------------------------------|--------------------------|
| -----<br>MMDDYYYY | -----<br>A2222 | -----<br>XXX,XXX         | -----<br>XXX,XXX,XX  | -----<br>XXX,XXX                   | -----<br>XXX,XXX,XX      |

SAMPLE

## SECTION 3113 DEMONSTRATION FEE SCHEDULE PAYMENT AMOUNT FILE

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## SECTION 3113 DEMONSTRATION FEE SCHEDULE PAYMENT AMOUNT FILE LAYOUT

| <u>DATA ELEMENT</u> | <u>LOCATION</u> | <u>COBOL PIC</u> | <u>DESCRIPTION</u>                                |
|---------------------|-----------------|------------------|---|
| DATA RECORD         |                 |                  |   |
| HCPCS Code          | 1-5             | x(5)             | CPT or Level 2 HCPCS code number for the service. |
| Locality            | 6-7             | x(2)             | Value for Locality will be "DE"                   |
| Payment Amount      | 8-17            | 9(7).99          | Pricing amount set by ORD1.                       |