CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-04 Medicare Claims Processing	Centers for Medicare & Medicaid Services (CMS)
Transmittal 3014	**Date: August 6, 2014**
	Change Request 8613

Transmittal 2904, dated March 14, 2014, is being rescinded and replaced by Transmittal 3014, dated August 6, 2014 to change the effective and implementation dates for ICD-10. Additionally, references to CMS contractor types have been replaced with Medicare Administrative Contractors (MACs) in the sections that are updated by this transmittal. Also, §40.3 has been updated to include information from Transmittal 2971, dated May 23, 2014. All other information remains the same.

SUBJECT: Update to Pub. 100-04, Chapter 16 to Provide Language-Only Changes for Updating ICD-10, ASC X12, and Medicare Administrative Contractors (MAC) Implementation

I. SUMMARY OF CHANGES: This Change Request (CR) contains language-only changes for updating ICD-10 and ASC X12 language in Pub 100-04, Chapter 16. There are no new coverage policies, payment policies, or codes introduced in this transmittal. Specific policy changes and related business requirements have been announced previously in various communications.

EFFECTIVE DATE:

ICD-10: Upon Implementation of ICD-10
ASC-X12: January 1, 2012

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

IMPLEMENTATION DATE:

ICD-10: Upon Implementation of ICD-10
ASC X12: September 8, 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.*

R/N/D	CHAPTER / SECTION / SUBSECTION / TITLE
R	16/Table of Contents
R	16/40.1.1.1/ Paper Claim Submission to A/B MACs (B)
R	16/40.1.1.2/ Electronic Claim Submission to A/B MACs (B)
R	16/40.3/ Hospital Billing Under Part B
R	16/50.3.2/ Hospital Laboratory Services Furnished to Nonhospital Patients
R	16/70.1/ Background
R	16/70.2/ Billing
R	16/70.10/ CLIA Number Submitted on Claims from Independent Labs
R	16/120.2/ Implementation and Updates of Negotiated National Coverage Determinations (NCDs) for Clinical Diagnostic Laboratory Services

III. FUNDING:

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

Attachment - Business Requirements

Pub. 100-04	Transmittal: 3014	Date: August 6, 2014	Change Request: 8613

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SUBJECT: Update to Pub. 100-04, Chapter 16 to Provide Language-Only Changes for Updating ICD-10, ASC X12, and Medicare Administrative Contractors (MAC) Implementation

EFFECTIVE DATE:
ICD-10: Upon Implementation of ICD-10
ASC-X12: January 1, 2012
**Unless otherwise specified, the effective date is the date of service.*

IMPLEMENTATION DATE:
ICD-10: Upon Implementation of ICD-10
ASC X12: 30 Days from issuance

I. GENERAL INFORMATION

A. Background: This Change Request (CR) contains language-only changes for updating ICD-10, ASC X12, and MAC language in Pub 100-04, Chapter 16.

B. Policy: There are no new coverage policies, payment policies, or codes introduced in this transmittal. Specific policy changes and related business requirements have been announced previously in various communications.

II. BUSINESS REQUIREMENTS TABLE

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

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
8613.1	A/B MACs shall be aware of the updated language for ICD-10 and for ASC X12 in Pub. 100 - 04, Chapter 16.	X	X							

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility

		A/B MAC			DME MAC	CEDI
		A	B	HHH		
	None					

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): Not Applicable

Post-Implementation Contact(s): Contact your Contracting Officer's Representative (COR).

VI. FUNDING

Section A: 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.

Medicare Claims Processing Manual
Chapter 16 - Laboratory Services

Table of Contents
(Rev.3014, Issued: 08-06-14)

40.1.1.1 - Paper Claim Submission to *A/B* MACs *(B)*

(Rev. 3014, Issued: 08-06-14, Effective: ICD- 10: Upon Implementation of ICD-10 ASC-X12: 01-01-12, Implementation: ICD-10: Upon Implementation of ICD-10 ASC X12: 09-08-14)

An independent clinical laboratory that *may* file a paper claim form shall file Form CMS-1500 for a referred laboratory service (as it would any laboratory service). The line item services must be submitted with a modifier 90.

An independent clinical laboratory that submits claims in paper format may not combine non-referred (i.e., self-performed) and referred services on the same CMS 1500 claim form. When the referring laboratory bills for both non-referred and referred tests, it shall submit two separate claims, one claim for non-referred tests, the other for referred tests. If billing for services that have been referred to more than one laboratory, the referring laboratory shall submit a separate claim for each laboratory to which services were referred (unless one or more of the reference laboratories are separately billing Medicare). A paper claim that contains both non-referred and referred tests is returned as unprocessable. When the referring laboratory is the billing laboratory, the reference laboratory's name, address, and ZIP Code shall be reported in item 32 on the CMS-1500 claim form to show where the service (test) was actually performed. The NPI shall be reported in item 32a. Also, the CLIA number of the reference laboratory shall be reported in item 23 on the CMS-1500 claim form. A paper claim that does not have the name, address, and ZIP Code of the reference laboratory in item 32 and NPI in 32a or the CLIA number of the reference laboratory in item 23 is returned as unprocessable.

EXAMPLE: A physician has ordered the ABC Laboratory to perform carcinoembryonic antigen (CEA) and hemoglobin testing for a patient. Since the ABC Laboratory is approved to perform tests only within the hematology LC level (which includes the hemoglobin test), it refers the CEA testing (which is a routine chemistry LC) to the XYZ laboratory.

Result: The ABC laboratory submits a claim for the hemoglobin test and reports its CLIA number in item 23 on the CMS-1500 form. Since the ABC laboratory referred the CEA test to the XYZ laboratory to perform, the ABC laboratory (billing laboratory) submits a second claim for the CEA testing, reporting XYZ's CLIA number in item 23 on the CMS-1500 form. The XYZ laboratory's name, address, and ZIP Code are also reported in item 32 and the NPI is reported in item 32a on Form CMS-1500 to show where the service (test) was actually rendered.

NOTE: When the reference laboratory is not located in the same billing jurisdiction as the referring laboratory, the referring (billing) laboratory shall use their own NPI for reporting purposes.

When a diagnostic service is billed as a purchased service and the service is purchased from another billing jurisdiction, the billing provider must submit their own NPI in Item 32a with the name, address, and ZIP Code of the performing provider in Item 32. The billing provider should keep a record of the performing provider's NPI in the clinical records for auditing purposes.

40.1.1.2 - Electronic Claim Submission to *A/B MACs (B)*

(Rev. 3014, Issued: 08-06-14, Effective: ICD- 10: Upon Implementation of ICD-10 ASC-X12: 01-01-12, Implementation: ICD-10: Upon Implementation of ICD-10 ASC X12: 09-08-14)

Electronic Claim Submission

ASC X12 837 professional claim format (HIPAA compliant version):

CLIA number:

An *electronic* claim for laboratory testing will require the presence of the performing (and billing) laboratory's CLIA number; if tests are referred to another laboratory, the CLIA number of the laboratory where the testing is rendered must also be on the claim. An electronic claim for laboratory testing must be submitted using the following *rules*:

Electronic claim: the billing laboratory performs all laboratory testing:

The independent laboratory submits a single claim for CLIA-covered laboratory tests and reports the billing laboratory's number in:

loop 2300, REF02. REF01 = X4

Electronic claim: billing laboratory performs some laboratory testing; some testing is referred to another laboratory:

The claim will not be split; CLIA numbers from both the billing and reference laboratories must be submitted on the same claim. The presence of the '90' modifier at the line item service identifies the referral tests. Referral laboratory claims are only permitted for independently billing clinical laboratories, specialty code 69.

The billing laboratory submits, on the same claim, tests referred to another (referral/rendered) laboratory, with modifier 90 reported on the line item and reports the referral laboratory's CLIA number in:

loop 2400, REF02. REF01 = F4

EXAMPLE: A physician has ordered the DEF independent laboratory to perform glucose testing and tissue typing for a patient. Since the DEF Laboratory is approved to perform only at the routine chemistry LC level (which includes glucose testing), it refers the tissue-typing test to the GHI laboratory.

The DEF laboratory submits a single claim for the glucose and tissue typing tests; the line item service for the glucose test is submitted without a '90' modifier since the DEF laboratory performed this test. The CLIA number for the DEF laboratory is entered in the electronic claim in:

loop 2300, REF02. REF01 = X4

On the same claim, the line item service for the tissue typing test is submitted with a '90' modifier and the referral/rendering GHI laboratory's CLIA number is entered on the electronic claim in:

loop 2400, REF02. REF01 = F4

Reference Laboratory's Address:

An electronic claim for laboratory testing requires the presence of the performing and billing laboratory's, name and address. The performing laboratory for a service with a line item CPT 90 modifier requires provider information for the appropriate 837 loop.

NOTE: When the reference laboratory is not located in the same billing jurisdiction as the referring laboratory, the referring (billing) laboratory shall use their own NPI for reporting purposes.

When a diagnostic service is billed as a purchased service and the service is purchased from another billing jurisdiction, the billing provider must submit their own NPI with the name, address, and ZIP Code of the performing provider in the appropriate data field. The billing provider should keep a record of the performing provider's NPI in the clinical records for auditing purposes.

40.3 - Hospital Billing Under Part B

(Rev. 3014, Issued: 08-06-14, Effective: ICD- 10: Upon Implementation of ICD-10 ASC-X12: 01-01-12, Implementation: ICD-10: Upon Implementation of ICD-10 ASC X12: 09-08-14)

Hospital laboratories, billing for either outpatient or non-patient claims, bill the *A/B* MAC *(A)*.

Neither deductible nor coinsurance applies to laboratory tests paid under the fee schedule.

Hospitals must follow requirements for submission of the ASC X12 *837 institutional claim* or the hardcopy Form CMS-1450. (*S*ee Chapter 25 for *a description of the data set, and for requirements for the paper form. See the ASC X12 837 implementation guide for billing requirements for the electronic claim,).*

When the hospital obtains laboratory tests for outpatients under arrangements with clinical laboratories or other hospital laboratories, only the hospital can bill for the arranged services.

As discussed in section 30.3 ("Place of Service Variation, Critical Access Hospitals") of this chapter, when the CAH bills a 14X bill type as a non-patient laboratory specimen, it is paid on the clinical laboratory fee schedule. For CAHs, payment for clinical diagnostic laboratory tests is made at 101 percent of reasonable cost only if the beneficiary is an outpatient of the CAH (85X TOB), as defined in 42 CFR 410.2, and is physically present in the CAH at the time the specimen is collected, for dates of service prior to July 1, 2009. However, for dates of service on or after July 1, 2009,

the beneficiary does not have to be physically present in the CAH at the time the specimen is collected as long as certain criteria are met, per Section 148 of the MIPPA (i.e. other outpatient services are received by the beneficiary in the CAH on the same day the specimen is collected, or the specimen is collected by an employee of the CAH or of a facility provider-based to the CAH) (see Section 30.3 above, Critical Access Hospital). Clinical diagnostic laboratory tests performed for a beneficiary who is not physically present at the CAH when the specimen is collected, by a non-CAH employee or who are not receiving other outpatient services in the CAH on the same day the specimen is collected, are paid are paid for under the clinical lab fee schedule. Similarly, for Maryland waiver hospitals, the waiver is limited to services to inpatients and registered outpatients as defined in 42 CFR 410.2. Therefore payment for non-patients (specimen only, TOB 14X) who are not registered outpatients at the time of specimen collection will be made on the clinical diagnostic laboratory fee schedule.

Section 416 of the Medicare Prescription, Drug, Improvement, and Modernization Act (MMA) of 2003 also eliminates the application of the clinical laboratory fee schedule for hospital outpatient laboratory testing by a hospital laboratory with fewer than 50 beds in a qualified rural area for cost reporting periods beginning during the 2-year period beginning on July 1, 2004. Payment for these hospital outpatient laboratory tests will be reasonable costs without coinsurance and deductibles during the applicable time period. A qualified rural area is one with a population density in the lowest quartile of all rural county populations.

The reasonable costs are determined using the ratio of costs to charges for the laboratory cost center multiplied by the PS&R's billed charges for outpatient laboratory services for cost reporting periods beginning on or after July 1, 2004 but before July 1, 2006.

In determining whether clinical laboratory services are furnished as part of outpatient services of a hospital, the same rules that are used to determine whether clinical laboratory services are furnished as an outpatient critical access hospital service will apply.

50.3.2 - Hospital Laboratory Services Furnished to Nonhospital Patients

(Rev. 3014, Issued: 08-06-14, Effective: ICD- 10: Upon Implementation of ICD-10 ASC-X12: 01-01-12, Implementation: ICD-10: Upon Implementation of ICD-10 ASC X12: 09-08-14)

When a hospital laboratory performs a laboratory service for a non-hospital patient, (i.e., for neither an inpatient nor an outpatient), the hospital bills its *A/B MAC (A)* on the *ASC X12 837 institutional claim format* or on the hard copy *F*orm CMS-1450. If an *A/B MAC (B)* receives such claims, the *A/B MAC (B)* should deny them. When the lab services are provided in Maryland, services to a hospital's own outpatients are paid under the State cost containment system. A Maryland hospital cannot seek payment based on a percent of charges for tests provided to individuals in locations such as a rural health clinic (RHC), a provider-based HHA, the individual's home or a physician's office). Individuals in these locations are non-patients of the Maryland

hospital and their lab tests would be categorized as “non-patient specimen only lab tests” (TOB 14x), and **are** paid under the lab fee schedule.

When a hospital-leased laboratory performs a service for a non-hospital patient, it must bill the *A/B MAC (B).*

70.1 - Background

(Rev. 3014, Issued: 08-06-14, Effective: ICD- 10: Upon Implementation of ICD-10 ASC-X12: 01-01-12, Implementation: ICD-10: Upon Implementation of ICD-10 ASC X12: 09-08-14)

The Clinical Laboratory Improvements Amendments of 1988 (CLIA), Public Law 100-578, amended §353 of the Public Health Service Act (PHSA) to extend jurisdiction of the Department of Health and Human Services to regulate all laboratories that examine human specimens to provide information to assess, diagnose, prevent, or treat any disease or impairment. The purpose of the CLIA program is to assure that laboratories testing specimens in interstate commerce consistently provide accurate procedures and services. As a result of CLIA, any laboratory soliciting or accepting specimens in interstate commerce for laboratory testing is required to hold a valid license or letter of exemption from licensure issued by the Secretary of HHS. The term “interstate commerce” means trade, traffic, commerce, transportation, or communication between any state, possession of the United States, the Commonwealth of Puerto Rico, or the District of Columbia, and any place outside thereof, or within the District of Columbia.

The CLIA mandates that virtually all laboratories, including physician office laboratories (POLs), meet applicable Federal requirements and have a CLIA certificate in order to receive reimbursement from Federal programs. CLIA also lists requirements for laboratories performing only certain tests to be eligible for a certificate of waiver or a certificate for Physician Performed Microscopy Procedures (PPMP). Since 1992, *A/B MACs (B)* have been instructed to deny clinical laboratory services billed by independent laboratories which did not meet the CLIA requirements. POLs were excluded from the 1992 instruction but included in 1997.

The CLIA number must be included on each *claim billed on the ASC X12 837 professional format or* Form CMS-1500 claim for laboratory services by any laboratory performing tests covered by CLIA. *See §70.2 and 70.10 for more information*.

70.2 - Billing

(Rev. 3014, Issued: 08-06-14, Effective: ICD- 10: Upon Implementation of ICD-10 ASC-X12: 01-01-12, Implementation: ICD-10: Upon Implementation of ICD-10 ASC X12: 09-08-14)

See §70.10 for instructions for reporting the CLIA number.

70.10 - CLIA Number Submitted on *Claims from Independent Labs*

(Rev. 3014, Issued: 08-06-14, Effective: ICD- 10: Upon Implementation of ICD-10 ASC-X12: 01-01-12, Implementation: ICD-10: Upon Implementation of ICD-10 ASC X12: 09-08-14)

Effective with services provided October 1, 1997, any independent laboratory performing tests covered by CLIA must submit the CLIA number on the *claim as provided below.* The CLIA number is reported in:

- ASC X12 837 *professional claim format* REF segment as REF02, with qualifier of "X4" in REF01, or
- Field 23 of the paper CMS-1500.

The CLIA number is not required on the *ASC X12 institutional claim data set or its related paper Form CMS-1450.*

See *C*hapter 26 for detailed format instructions for the paper claim CMS-1500.

Laboratory claims submitted without the *required* CLIA number are returned as unprocessable. If the CLIA number is submitted on the claim, but is inconsistent with the CLIA format, the *A/B MAC (B)* returns the claim as unprocessable. If more than one CLIA number is submitted on the claim, except when a reference laboratory is on the same claim, the *A/B MAC (B)* returns the claim as unprocessable.

If the tests on one claim have been performed in more than one Physician Office Laboratory (POL) by the same physician, the appropriate CLIA number should be associated with the test that was performed in each laboratory. In such a case, the physician must submit a separate claim for each location (CLIA number) where a test was performed

120.2 - Implementation and Updates of Negotiated National Coverage Determinations (NCDs) for Clinical Diagnostic Laboratory Services

(Rev. 3014, Issued: 08-06-14, Effective: ICD- 10: Upon Implementation of ICD-10 ASC-X12: 01-01-12, Implementation: ICD-10: Upon Implementation of ICD-10 ASC X12: 09-08-14)

Under a negotiated rulemaking process, the Center for Medicare & Medicaid Services (CMS) developed 23 NCDs for clinical diagnostic laboratory services. The NCDs are applicable to services billed under Part B regardless of the entity providing the services. Thus, they are binding on *A/B MACs (A and B)* in processing clinical diagnostic laboratory services on an outpatient basis.

In order to ensure uniformity in the implementation of the NCDs, CMS developed the NCDs utilizing three lists of diagnosis codes. Every diagnosis code will fall into one the three lists. The lists included: Codes Covered by Medicare, Codes Denied, and Codes That Do Not Support Medical Necessity.

Related software, called the laboratory edit module, *is* incorporated in the shared systems so that laboratory claims subject to one of the 23 NCDs are processed uniformly throughout the nation.

In addition, the NCDs are maintained through the NCD process that was announced in the "Federal Register" on September 26, 2003 (68 FR 55634). This process provides for public participation through a comment period at the beginning of the evaluation of the issue and includes a detailed decision document that outlines the rationale for the decision. These documents may be viewed on the Medicare coverage homepage at cms.hhs.gov/coverage.

On a quarterly basis, CMS will update the NCD edit module as necessary for ministerial coding changes and to implement the NCD decisions described above. *CMS assures the updated software is communicated* to the shared system maintainers. The shared system maintainers install the revised edit module after testing and distribute it to the *A/B MACs (A and B)* as part of their routine release. *A/B MACs (A and B)* will conduct provider education to advise the laboratories of changes to the laboratory edit module quarterly.