CMS Manual System	**Department of Health & Human Services (DHHS)**
Pub 100-04 Medicare Claims Processing	**Centers for Medicare & Medicaid Services (CMS)**
Transmittal 1940	**Date: April 2, 2010**
	Change Request 6873

SUBJECT: Extension of Reasonable Cost Payment for Clinical Lab Tests Furnished by Hospitals with Fewer Than 50 Beds in Qualified Rural Areas

I. SUMMARY OF CHANGES: This CR provides instruction to extend reasonable cost payment for clinical lab tests performed by hospitals with fewer than 50 beds in qualified rural areas as part of their outpatient services for cost reporting periods beginning on or after July 1, 2010, through June 30, 2011.

EFFECTIVE DATE: For cost reporting periods beginning on or after July 1, 2010, through June 30, 2011
IMPLEMENTATION DATE: July 6, 2010

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	16/30.3 - Method of Payment for Clinical Laboratory Tests - Place of Service Variation

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: 1940	Date: April 2, 2010	Change Request: 6873

SUBJECT: Extension of Reasonable Cost Payment for Clinical Lab Tests Furnished by Hospitals with Fewer Than 50 Beds in Qualified Rural Areas

Effective Date: For cost reporting periods beginning on or after July 1, 2010, through June 30, 2011

Implementation Date: July 6, 2010

I. GENERAL INFORMATION

A. Background:

Section 416 of the Medicare Modernization Act (MMA) of 2003

CMS issued Change Request (CR) 3130 on February 13, 2004, to implement procedures to provide reasonable cost payment for outpatient clinical laboratory tests furnished by hospitals with fewer than 50 beds in qualified rural areas for cost reporting periods beginning during the 2-year period beginning on July 1, 2004.

Section 105 of the Tax Relief and Health Care Act (TRHCA) of 2006

On February 2, 2007, CMS issued CR 5493 to extend the 2-year provision outlined within CR 3130 for an additional cost-reporting year. Because CR 5493 was implemented beyond the original sun-setting date outlined in CR 3130, contractors were instructed to adjust any claims for laboratory services that should have received reasonable cost payment under Section 105 of the TRHCA.

Section 107 of the Medicare, Medicaid and State Children's Health Insurance Program (SCHIP) Extension Act of 2007

Section 107 of this Act extended reasonable cost payment for clinical lab tests performed by hospitals with fewer than 50 beds in qualified rural areas as part of their outpatient services for cost reporting periods beginning on or after July 1, 2004, through June 30, 2008. For some hospitals, this affected services performed as late as June 30, 2009.

B. Policy:

Section 3122 of the Patient Protection and Affordable Care Act re-institutes reasonable cost payment for clinical lab tests performed by hospitals with fewer than 50 beds in qualified rural areas as part of their outpatient services for cost reporting periods beginning on or after July 1, 2010, through June 30, 2011. For some hospitals, this could affect services performed as late as June 30, 2012.

II. BUSINESS REQUIREMENTS TABLE

"Shall" denotes 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	
6873.1	The Fiscal Intermediary Standard System shall utilize the Medicare Zip Code File to identify qualified rural areas. Note: A qualified rural area in the context of this CR is one with a population density in the lowest quartile of all rural county populations.						X				

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	
6873.2	Effective for an entire cost reporting period beginning on or after July 1, 2010, through June 30, 2011, contractors shall update the Special Locality Indicator field within the Outpatient Provider Specific File (OPSF) with an indicator of '1' to identify hospitals in a qualified rural area that have fewer than 50 beds.	X		X							
6873.3	Effective for an entire cost reporting period beginning on or after July 1, 2010, through June 30, 2011, contractors shall calculate payment on a reasonable cost basis for outpatient clinical laboratory services from qualified hospitals.	X		X			X				
6873.3.1	Contractors shall calculate reasonable cost payment for services on a Revenue Code 030X line submitted on either a 12X or 13X Type of Bill (TOB).	X		X			X				
6873.4	Contractors shall not hold the beneficiary liable for any deductible, coinsurance, or any other cost-sharing amount.	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	
6873.5	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							

IV. SUPPORTING INFORMATION

Section A: Any recommendations and supporting information associated with listed requirements: N/A
"Should" denotes a recommendation.

X-Ref Requirement Number	Recommendations or other supporting information:
None	

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

V. CONTACTS

Pre-Implementation Contact(s): Joe Bryson at 410-786-2986 or joseph.bryson@cms.hhs.gov

Post-Implementation Contact(s): Regional Office

VI. FUNDING

Section A: 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.

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.

Medicare Claims Processing Manual
Chapter 16 - Laboratory Services

30.3 - Method of Payment for Clinical Laboratory Tests - Place of Service Variation

(Rev.1940, Issued: 04-02-10, Effective: 07-01-10, Implementation: 07-06-10)

The following apply in determining the amount of Part B payment for clinical laboratory tests, including those furnished under method II for ESRD beneficiaries:

Independent laboratory or a physician or medical group - Payment to an independent laboratory or a physician or medical group is the lesser of the actual charge, the fee schedule amount or the national limitation amount. Part B deductible and coinsurance do not apply.

Reference laboratory - For tests performed by a reference laboratory, the payment is the lesser of the actual charge by the billing laboratory, the fee schedule amount, or the national limitation amount (NLA). (See §50.5 for carrier jurisdiction details.) Part B deductible and coinsurance do not apply.

Outpatient of the hospital - Payment to a hospital for laboratory tests payable on the Clinical Diagnostic Laboratory Fee Schedule, furnished to an outpatient of the hospital, is the lesser of the actual charge, fee schedule amount, or the NLA. Part B deductible and coinsurance do not apply. Laboratory tests not payable on the Clinical Diagnostic Laboratory Fee Schedule will be based on OPPS (for hospitals subject to OPPS) and current methodology for hospitals not subject to OPPS.

Exception: Reasonable cost reimbursement has been provided for outpatient clinical laboratory tests furnished by hospitals with fewer than 50 beds in qualified rural areas for cost reporting periods beginning on July 1, 2004 through 2008 (per the following legislation: Section 416 of the Medicare Modernization Act (MMA) of 2003, Section 105 of the Tax Relief and Health Care Act (TRHCA) of 2006, and Section 107 of the Medicare, Medicaid and State Children's Health Insurance Program (SCHIP) Extension Act of 2007). Section 3122 of the Patient Protection and Affordable Care Act re-institutes the above reasonable cost provisions for cost reporting periods beginning on or after July 1, 2010, through June 30, 2011.

Non-Patient Laboratory Specimen-Laboratory tests payable on the Clinical Diagnostic Laboratory Fee Schedule for a non-patient laboratory specimen (bill type 14X) is the lesser of the actual charge, the fee schedule amount, or the NLA (including MD Waiver hospitals). Part B deductible and coinsurance do not apply. Laboratory tests not payable on the Clinical Diagnostic Laboratory Fee Schedule will be based on OPPS (for hospitals subject to OPPS) or the current methodology for hospitals not subject to OPPS.

Inpatient without Part A - Payment to a hospital for laboratory tests payable on the Clinical Diagnostic Laboratory Fee Schedule, is the lesser of the actual charge, fee schedule amount, or the NLA. Part B deductible and coinsurance do not apply. Laboratory tests not payable on the Clinical Diagnostic Laboratory Fee Schedule will be based on OPPS (for hospitals subject to OPPS) and current methodology for hospitals not subject to OPPS. Payment to a SNF inpatient without Part A coverage is made under the laboratory fee schedule.

Inpatient or SNF patient with Part A - Payment to a hospital for laboratory tests furnished to an inpatient, whose stay is covered under Part A, is included in the PPS rate for PPS facilities or is made on a reasonable cost basis for non-PPS hospitals and is made at 101 percent of reasonable cost for CAHs. Payments for lab services for beneficiaries in a Part A stay in a SNF, other than a swing bed in a CAH are included in the SNF PPS rate. For such services provided in a swing bed of a CAH, payment is made at 101 percent of reasonable cost.

Sole community hospital - Payment to a sole community hospital for tests furnished for an outpatient of that hospital is the least of the actual charge, the 62 percent fee schedule amount, or the 62 percent NLA. The Part B deductible and coinsurance do not apply.

Waived Hospitals - Payment for outpatient (bill type13X), to a hospital which has been granted a waiver of Medicare payment principles for outpatient services is subject to Part B deductible and coinsurance unless otherwise waived as part of an approved waiver. Specifically, laboratory fee schedules do not apply to laboratory tests furnished by hospitals in States or areas that have been granted demonstration waivers of Medicare reimbursement principles for outpatient services. The State of Maryland has been granted such demonstration waivers. Payment for non-patient laboratory specimens (bill type14X) is based on the fee schedule**.** Laboratory tests not payable on the Clinical Diagnostic Laboratory Fee Schedule will be paid based on current methodology.

Critical Access Hospital - When the CAH bills a 14X bill type as a non-patient laboratory specimen, it is paid on the laboratory fee schedule.

Beneficiaries are not liable for any coinsurance, deductible, co-payment, or other cost sharing amount with respect to CAH clinical laboratory services.

Section 148 of The Medicare Improvements for Patients and Providers Act (MIPPA)

A CAH will be paid 101 percent of reasonable cost for outpatient clinical diagnostic laboratory tests. Effective for services furnished on or after July 1, 2009, the individual is no longer required to be physically present in a CAH at the time the specimen is collected. However, the individual must be an outpatient of the CAH, as defined at 42 CFR §410.2 and be receiving services directly from the CAH. In order for the individual to be receiving services directly from the CAH, the individual must either be receiving outpatient services in the CAH on the same day the specimen is collected, or the specimen must be collected by an employee of the CAH or of a facility provider-based to the CAH.

Dialysis facility - Payment to a hospital-based or independent dialysis facility for laboratory tests included under the ESRD composite rate payment and performed for a patient of that facility, is included in the facility's composite rate payment for these tests and is subject to the Part B deductible and coinsurance. Laboratory tests that are not included under the ESRD composite rate payment; and are performed by an independent laboratory or a hospital-based laboratory for dialysis patients of independent dialysis facilities or hospital based facilities; are paid in addition to the composite rate payment and are subject to the fee schedule limits. This also applies to all laboratory tests furnished to home dialysis patients who have selected Payment Method II. (See §40.3 for details on Part B hospital billing rules for laboratory services and §40.6 for details on ESRD billing.)

Rural Health Clinic (RHC)/Federally Qualified Health Center (FQHC) - Payment to a RHC/FQHC for laboratory tests performed for a patient of that clinic/center is not included in the all-inclusive rate and may be billed separately by either the base provider for a provider-based RHC/FQHC, or by the physician for an independent or free-standing RHC/FQHC. Payment for the laboratory service is not subject to Part B deductible and coinsurance. If the RHC/FQHC is provider-based, payment for lab tests is to the base provider (i.e., hospital). If the RHC/FQHC is independent or freestanding, payment for lab tests is made to the practitioner (physician) via the clinical lab fee schedule. (See Sections 30.1.1 and 40.5 for details on RHC/FQHC billing.)

Enrolled in Managed Care - Payment to a participating health maintenance organization (HMO) or health care prepayment plan (HCPP) for laboratory tests provided to a Medicare beneficiary who is an enrolled member is included in the monthly capitation amount.

Non-enrolled Managed Care - Payment to a participating HMO or HCPP for laboratory tests performed for a patient who is not a member is the lesser of the actual charge, or the fee schedule, or the NLA. The Part B deductible and coinsurance do not apply.

Hospice - Payment to a hospice for laboratory tests performed by the hospice is included in the hospice rate.