CMS Manual System	**Department of Health & Human Services (DHHS)**
Pub 100-04 Medicare Claims Processing	**Centers for Medicare & Medicaid Services (CMS)**
Transmittal 3653	**Date: November 10, 2016**
	Change Request 9837

SUBJECT: FISS Implementation of the Restructured Clinical Lab Fee Schedule

I. SUMMARY OF CHANGES: This Change Request (CR) instructs the Fiscal Intermediary Shared System (FISS) to incorporate into the shared system, the revised Clinical Lab Fee Schedule (CLFS) containing the National fee schedule rates.

EFFECTIVE DATE: January 1, 2018
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: April 3, 2017 - For requirements, design, and coding; July 3, 2017 - For testing and implementation

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
N/A	N/A

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 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:

Attachment

Pub. 100-04	Transmittal: 3653	Date: November 10, 2016	Change Request: 9837

SUBJECT: FISS Implementation of the Restructured Clinical Lab Fee Schedule

EFFECTIVE DATE: January 1, 2018
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I. GENERAL INFORMATION

A. Background: Section 216 of Public Law 113-93, the "Protecting Access to Medicare Act of 2014," added section 1834A to the Social Security Act (the Act). This provision requires extensive revisions to the payment and coverage methodologies for clinical laboratory tests paid under the clinical laboratory fee schedule (CLFS). The Centers for Medicare & Medicaid Services (CMS) published [Final Rule citation], which implemented the provisions of the new legislation.

The final rule set forth new policies for how CMS sets rates for tests on the CLFS and is effective for dates of service on and after January 1, 2018. Beginning on January 1, 2017, applicable laboratories will be required to submit data to CMS which describes negotiated payment rates with private payers for and corresponding volumes of tests on the CLFS. In general, with certain designated exceptions, the payment amount for a test on the CLFS furnished on or after January 1, 2018, will be equal to the weighted median of private payer rates determined for the test, based on data collected from laboratories during a specified data collection period. In addition, a subset of tests on the CLFS, advanced diagnostic laboratory tests (ADLTs), will have different data, reporting, and payment policies associated with them. In particular, the final rule discusses CMS' proposals regarding:

- Definition of "applicable laboratory" (who must report data under section 1834A of the Act)
- Definition of "applicable information" (what data will be reported)
- Data collection period
- Schedule for reporting data to CMS
- Definition of ADLT
- Data Integrity
- Confidentiality and public release of limited data
- Coding for new tests on the CLFS
- Phased in payment reduction

In anticipation of rulemaking and in preparation for implementation of the new CLFS, CMS engaged with contractors in analysis and design activities related to implementation of the new CLFS. Two workgroups were established to discuss the Part A and Part B shared systems. Shared system maintainers provided analysis and design documents based on the outcome of those discussions.

B. Policy: This Change Request (CR) instructs the Fiscal Intermediary Shared System (FISS) to incorporate into the shared system, the revised Clinical Lab Fee Schedule (CLFS) process containing the National fee schedule rates. Based on the alternatives provided in FISS' analysis deliverable, CMS is

electing to implement Alternative #1.

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	
9837.1	Contractors shall modify the HCPCS load process to incorporate the new CLFS file layout in Attachment A into the current load process.					X				
9837.1.1	Contractors shall note that the new CLFS will be delivered in the same manner as is used for the current CLFS and will have the following file name: MU00.@BF12394.RCLAB.CY##.V####.FI Note: "CY##" will represent the calendar year for which the file applies and "V####" will represent the release date of the file.					X				VDCs
9837.1.2	Contractors shall accept the CLFS according to the following specifications: @1 Year $CHAR4. @6 HCPCS Code $CHAR5. @12 Modifier $CHAR2. @15 Effective Date $CHAR8. @24 Indicator $CHAR1. @26 Payment Rate Z8.2 @35 Description $CHAR40.					X				
9837.1.3	Contractors shall modify the HCPCS load process to read the National/Local indicator from the CLFS file.					X				
9837.1.3.1	For HCPCS with an indicator equal to 'L', contractors shall apply the new National default carrier code without a payment rate and include a pricing indicator of 'Z' on the HCPCS record.					X				

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
9837.1.3.2	For HCPCS with an indicator equal to 'N', contractors shall apply the new National default carrier code with the payment rate indicated on the CLFS.					X				
9837.1.4	Contractors shall populate the National rate in the 60% and 62% pricing fields.					X				
9837.1.5	Contractors shall review any previously established local pricing as needed for HCPCS identified as UPDATED on the "CLFS Local HCPCS – Added/Updated" report.	X								
9837.2	Contractors shall create a new carrier/locality code of 00000/01 as the default National carrier.					X				
9837.2.1	Contractors shall assign existing reason code 32404 for claims with line item dates of service on or after January 1, 2018, containing lab HCPCS not found for carrier 00000 and locality 01.					X				
9837.3	Effective for claims with dates of service on or after January 1, 2018, contractors shall modify the logic for claim line items containing revenue code 030X or 031X to use the 60% rate for national HCPCS codes or use the rate entered on the claim line by the MACs for local HCPCS with a pricing indicator of 'Z'.					X				
9837.4	Effective for claims with line item dates of service on and after January 1, 2018, contractors shall bypass existing CLFS pricing logic for all claims containing lab HCPCS.					X				
9837.4.1	Contractors shall continue to process claims containing lab HCPCS for dates of service prior to January 1, 2018, using existing CLFS pricing logic.					X				
9837.4.2	Contractors shall ensure that adjustment claims containing lab HCPCS follow the same date of service driven logic as the original claim.					X				
9837.4.3	Contractors shall modify edits, as necessary, to allow claims with dates of service on and after January 1, 2018 to bypass the existing CLFS pricing logic.					X				
9837.5	Effective for claims with line item dates of service on and after January 1, 2018, contractors shall ensure that Sole Community Hospital (SCH) claim lines	X				X				

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
	containing lab HCPCS are priced at the national (00000/01) rate or the rate entered by the MAC for local HCPCS with a pricing indicator of 'Z'.									
9837.5.1	Contractors shall continue to process SCH claims containing lab HCPCS for dates of service prior to January 1, 2018 using existing SCH pricing logic.					X				
9837.5.2	Contractors shall ensure that SCH adjustment claims follow the same logic for pricing of lab HCPCS as the original claim.					X				
9837.5.3	Contractors shall continue to price all other (non-lab) lines on SCH claims according to existing SCH logic.					X				
9837.6	Effective for claims with line item dates of service on and after January 1, 2018, contractors shall not bundle or roll up individually billed lab test HCPCS to a lab panel HCPCS or an ATP code, however, contractors shall continue to apply editing to ensure that if a lab panel HCPCS is submitted and allowed, an individual lab HCPCS that is part of the same panel is not also allowed. Note: Editing on services with repeat service modifiers (e.g., -91) will continue with the current logic as well.					X				
9837.7	Effective for claims with line item dates of service on and after January 1, 2018, contractors shall discontinue specialized pricing logic for ATP multi-channel tests.					X				
9837.7.1	Contractors shall continue to apply ATP pricing and roll-up logic to claims for dates of service prior to January 1, 2018.					X				
9837.7.2	Contractors shall ensure that ATP adjustment claims follow the same date of service driven logic as the original claim.					X				
9837.8	Contractors shall create a new quarterly report called "CLFS Local HCPCS – Added/Updated" to identify HCPCS on the CLFS that require local pricing.					X				

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
9837.8.1	Contractors shall include in the report all HCPCS on the CLFS with a National/Local indicator equal to 'L'.					X				
9837.8.2	Contractors shall include the following data elements in the report: Report Header: 1. Run Date 2. Report Number 3. Intermediary Number 4. Page Report Detail: 1. HCPCS 2. HCPCS modifier(s) 3. Effective Date 4. Short Descriptor 5. Rate 6. Comment "ADDED" or "UPDATED" 7. Previous Rate (if it is an update and the rate on the incoming CLFS is different than the existing rate on file) 8. Previous Indicator (if it is an update and the new indicator is different than the previous indicator)					X				
9837.9	Contractors shall create a new quarterly report called "CLFS National HCPCS – Added/Updated" to identify newly added or updated HCPCS from the CLFS file.					X				
9837.9.1	Contractors shall include in the report any HCPCS on the CLFS with a National/Local indicator equal to 'N' and that was either:					X				

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
	• New on the CLFS file; or • An existing record on the CLFS that has been modified in some way (for example, the effective date or rate is changed)									
9837.9.2	Contractors shall include the following data elements in the report: Report Header: 1. Run Date 2. Report Number 3. Intermediary Number 4. Page Report Detail: 1. HCPCS 2. HCPCS modifier(s) 3. Effective Date 4. Short Descriptor 5. Rate 6. Comment "ADDED" or "UPDATED" 7. Previous Rate (if it is an update and the new rate is different than the previous rate) 8. Previous Indicator (if it is an update and the new indicator is different than the previous indicator)					X				
9837.10	Contractors shall modify system logic to grab/load the Provider Carrier/Locality HCPCS record and the default National Carrier/Locality HCPCS record associated with the HCPCS on the claim.					X				
9837.10.1	Contractors shall not grab/load the default National Carrier/Locality HCPCS record if the date of service					X				

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
	on the claim is prior to January 1, 2018.									
9837.11	Contractors shall receive a test file for alpha testing no later than February 28, 2017.					X				
9837.12	Contractors shall notify CMS immediately of any issues with the CLFS file or data contained in the file.	X				X				

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility				
		A/B MAC			DME MAC	CEDI
		A	B	HHH		
9837.13	MLN Article: A provider education article related to this instruction will be available at http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/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 sites and include information about it in a listserv message within 5 business days after receipt of the notification from CMS announcing the availability of the article. In addition, the provider education article shall be included in the contractor's next regularly scheduled bulletin. Contractors are free to supplement MLN Matters articles with localized information that would benefit their provider community in billing and administering the Medicare program correctly.	X				

IV. SUPPORTING INFORMATION

Section A: Recommendations and supporting information associated with listed requirements:

"Should" denotes a recommendation.

X-Ref Requirement Number	Recommendations or other supporting information:
	N/A

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

V. CONTACTS

Pre-Implementation Contact(s): Felicia Rowe, felicia.rowe@cms.hhs.gov (For institutional claims processing issues) , Sarah Harding, sarah.harding@cms.hhs.gov (For policy related issues) , Craig Dobyski, craig.dobyski@cms.hhs.gov (For policy related issues) , Jared Frank, jared.frank@cms.hhs.gov (For technical issues related to the CLFS)

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.

ATTACHMENTS: 2

2017 Clinical Diagnostic Laboratory Fee Schedule

HCPCS	Modifier	Effective Date	National / Local Indicator	Payment Rate (PR)	SHORTDESC
ADLT1		20170101	N	50.08	ADLT1 Descriptor
ADLT2		20170101	N	200.50	ADLT2 Descriptor
NAT1		20170101	N	86.00	NAT1 Descriptor
NAT2	QW	20170101	N	86.00	NAT2 Descriptor
GAP1		20170101	L	0.00	GAP1 Descriptor
GAP2		20170101	L	0.00	GAP2 Descriptor

2017~ADLT1~ ~20170101~N~00050.08~ADLT1 Descriptor
2017~ADLT2~ ~20170101~N~00200.50~ADLT2 Descriptor
2017~NAT1 ~ ~20170101~N~00086.00~NAT1 Descriptor
2017~NAT2 ~QW~20170101~N~00086.00~NAT2 Descriptor
2017~GAP1 ~ ~20170101~L~00000.00~GAP1 Descriptor
2017~GAP2 ~ ~20170101~L~00000.00~GAP2 Descriptor