

<b>CMS Manual System</b>	<b>Department of Health &amp; Human Services (DHHS)</b>
<b>Pub 100-20 One-Time Notification</b>	<b>Centers for Medicare &amp; Medicaid Services (CMS)</b>
<b>Transmittal 2282</b>	<b>Date: April 25, 2019</b>
	<b>Change Request 11271</b>

**Transmittal 2279, dated April 12, 2019, is being rescinded and replaced by Transmittal 2282, dated, April 25, 2019 to add specialty hospitals to business requirements 11271.1 and 11271.2 for the CLFS mailing and to extend the effective and implementation dates. All other information remains the same.**

**SUBJECT: Direct Mailing Notification to the Medicare Administrative Contractors (MACs) Regarding Clinical Laboratory Fee Schedule (CLFS)**

**I. SUMMARY OF CHANGES:** Notification about an upcoming direct mailing to be completed by MACs on CLFS changes to be completed by MACs.

**EFFECTIVE DATE: May 10, 2019**

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

**IMPLEMENTATION DATE: May 10, 2019**

*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.*

<b>R/N/D</b>	<b>CHAPTER / SECTION / SUBSECTION / TITLE</b>
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:**

**One Time Notification**

# Attachment - One-Time Notification

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**SUBJECT: Direct Mailing Notification to the Medicare Administrative Contractors (MACs) Regarding Clinical Laboratory Fee Schedule (CLFS)**

**EFFECTIVE DATE: May 10, 2019**

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**IMPLEMENTATION DATE: May 10, 2019**

**I. GENERAL INFORMATION**

**A. Background:** Direct Mailing from the MACs related to CLFS changes.

**B. Policy:** The Protecting Access to Medicare Act of 2014.

**II. BUSINESS REQUIREMENTS TABLE**

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

Number	Requirement	Responsibility									
		A/B MAC			D M E	Shared- System Maintainers				Other	
		A	B	H H H		F M V C S	M I C S	V M S	C W F		
11271.1	MACs shall identify all active independent labs, all hospitals, including specialty hospitals within their jurisdiction and determine the best mailing address on file in accordance with Internet Only Manual publication 100-09, chapter 6, section 20.4.2.	X	X								
11271.2	MACs shall send a letter to all independent labs, all hospitals, including specialty hospitals using the best mailing address on file, taking the following actions: <ol style="list-style-type: none"> <li>1. Download the letter from eChimp Word (both Word and PDF versions will be provided).</li> <li>2. Apply provider mailing addresses either directly to the letter or use address inserts.</li> <li>3. Duplicate the letter in hard copy using the same MAC letterhead used to produce provider correspondence making no alterations to the letter beyond the insertion of addresses.</li> <li>4. Duplicate the letter using black font.</li> <li>5. Use envelopes typically used to send provider correspondence.</li> </ol>	X	X								

Number	Requirement	Responsibility								Other
		A/B MAC			D M E M A C	Shared- System Maintainers				
		A	B	H H H		F I S S	M C S	V M S	C W F	
	6. Send a single letters to groups.									
11271.3	MACs shall complete the direct mailing no later than 10 business days from the date the CR is issued.	X	X							
11271.4	MACs shall report the following information about this direct mailing in an e-mail titled Clinical Laboratory Fee Schedule to the Provider Services mailbox at providerservices@cms.hhs.gov within one business day of completing the mailing:  1. Date completed 2. Number of letters sent	X	X							
11271.5	MACs shall report the following information about this direct mailing into the Clinical Laboratory Fee Schedule portion of the Provider Customer Service Program Contractor Information Database (PCID) by the 10th of the month following the month of the actual completion date:  1. Date completed 2. Number of letters sent 3. Number of providers covered by letters sent 4. Number of letters returned 5. Cost	X	X							
11271.6	MACs shall track and report undeliverable packages for 3 months after the packages are mailed.	X	X							
11271.6.1	If MACs need to change the numbers reported in PCID, corrections shall be sent to the PCID resource mailbox at pcid@cms.hhs.gov.	X	X							
11271.6.2	MACs shall not make multiple entries into PCID regarding this direct mailing.	X	X							
11271.7	MACs shall follow their standard internal procedures concerning undeliverable mail.	X	X							

### III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility				
		A/B MAC			D M E	C E D I
		A	B	H H H		
					M A C	
	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):** Paul Zawicki, Paul.Zawicki@cms.hhs.gov , Angela Di Giorgio, Angela.digiorgio1@cms.hhs.gov

**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: 1**

Dear Clinical Laboratories and Hospitals:

The Protecting Access to Medicare Act of 2014 required significant changes to how Medicare pays for clinical diagnostic laboratory tests under the Clinical Laboratory Fee Schedule (CLFS). Effective January 1, 2018, the payment amount for most tests equals the weighted median of private payor rates. Payment rates under the private payor rate-based CLFS are updated every three years. Therefore, CMS needs private payor data to set payment rates effective January 1, 2021. Are you required to submit data?

- If you are a laboratory, including an independent laboratory, a physician office laboratory or hospital outreach laboratory that meets the definition of an applicable laboratory then you are required to report information which includes laboratory test HCPCS codes, associated private payor rates, and volume data.

If you meet the applicable laboratory criteria, act now using this schedule:

- January – June, 2019: Collect data
- July – December, 2019: Analyze data
- January – March, 2020: Report data

Going forward, applicable laboratories must submit data every three years.

Visit our webpage (<https://go.usa.gov/xEdM8>) for resources, including how to determine whether your laboratory is an applicable laboratory, how to report data and examples of who must report. Submit questions to [CLFS\\_Inquiries@cms.hhs.gov](mailto:CLFS_Inquiries@cms.hhs.gov). We appreciate your time and effort.