CMS Manual System	Department of Health & Human Services (DHHS)				
Pub 100-20 One-Time Notification	Centers for Medicare & Medicaid Services (CMS)				
Transmittal 11001	Date: September 16, 2021				
	Change Request 12452				

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

I. SUMMARY OF CHANGES: The purpose of this change request (CR) notifies upcoming direct mailings to be completed by MACs on CLFS changes.

EFFECTIVE DATE: September 30, 2021

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

IMPLEMENTATION DATE: September 30, 2021

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:

One Time Notification

Attachment - One-Time Notification

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EFFECTIVE DATE: September 30, 2021

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I. GENERAL INFORMATION

A. Background: 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.

NOTE: This mailing is not included in the work outlined in IOM Pub 100-09, Chapter 6 Section 20.4.2.

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	Re	spoi	nsibility	,						
		A/B MAC		A/B MAC DME			E Shared-System Maintainers				
		A	В	ННН	MAC	FISS	MCS	VMS	CWF		
12452.1	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								
12452.2	MACs shall not make multiple entries into PCID regarding this direct mailing.	X	X								
12452.3	MACs shall complete the direct mailing no later than 10 business days from the date the CR is issued.	X	X								
12452.4	MACs shall track and report undeliverable packages for 3 months after the packages are	X	X								

Number	Requirement	Responsibility								
	-	A/B MAC		DME Shared-System Maintainer					Other	
		A	В	ННН	MAC	FISS	MCS	VMS	CWF	
	mailed.									
12452.5	MACs shall send a letter to all independent labs, hospitals and specialty hospitals using the mailing address on file: 1. The letter will be coming via the PCUG Listserv. 2. Apply provider mailing addresses directly to the letter or use address inserts. 3. Duplicate the letter in hard copy using black font and the same MAC letterhead used to produce provider correspondence, making no alterations to the letter beyond the insertion of addresses. 4. Duplicate the letter using black font. 5. Use envelopes typically used to send provider correspondence. 6. Send a single package to groups.	X	X							
12452.6	If MACs need to change the numbers reported in PCID, the MACs shall send corrections to the PCID resource mailbox at pcid@cms.hhs.gov.	X	X							
12452.7	MACs shall follow their standard internal procedures concerning undeliverable mail.	X	X							
12452.8	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	X	X							

Number	Requirement	Responsibility								
		A	A/B MAC DME Shar			Share	Shared-System Maintainers			
		A	В	ННН	MAG	FISS	MCS	VMS	CWF	
	completing the mailing.				MAC					
	completing the mailing:									
	1. Date completed									
	2. Number of letters sent									
12452.9	MACs shall report the following information about this direct mailing into the Clinical Laboratory Fee Schedule portion of 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							

III. PROVIDER EDUCATION TABLE

Number	Requirement	R	espo	nsibility	7	
			A	/B	DME	CEDI
				AC		
			1_		MAC	
		A	В	ННН		
	None					

IV. SUPPORTING INFORMATION

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

[&]quot;Should" denotes a recommendation.

X-Ref	Recommendations or other supporting information:
Requirement	
Number	

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

V. CONTACTS

Pre-Implementation Contact(s): Angela Di Giorgio, 410-786-4516 or 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):

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ATTACHMENTS: 0