CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-20 One-Time Notification	Centers for Medicare & Medicaid Services (CMS)
Transmittal 10798	Date: May 20, 2021
	Change Request 12294

SUBJECT: Addition of the Shared System CWF to the Business Requirements for the Healthcare Common Procedure Coding System (HCPCS) codes U0002QW and 87635QW Mentioned in Change Request 11765

I. SUMMARY OF CHANGES: This change informs Medicare contractors about a revision to Change Request 11765, transmittal R10066OTN, that adds the shared system CWF to the business requirements for the Healthcare Common Procedure Coding System (HCPCS) codes U0002QW and 87635QW. All other information in Change Request 11765 remains unchanged. This One Time Notification applies to Chapter 16, Section 70.9.

EFFECTIVE DATE: March 20, 2020

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

IMPLEMENTATION DATE: July 6, 2021 - (fast tracked-May 10, 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		

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

Pub. 100-20	Transmittal:10798	Date: May 20, 2021	Change Request: 12294
-------------	-------------------	---------------------------	------------------------------

SUBJECT: Addition of the Shared System CWF to the Business Requirements for the Healthcare Common Procedure Coding System (HCPCS) codes U0002QW and 87635QW Mentioned in Change Request 11765

EFFECTIVE DATE: March 20, 2020

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

IMPLEMENTATION DATE: July 6, 2021 - (fast tracked-May 10, 2021)

I. GENERAL INFORMATION

A. Background: The Clinical Laboratory Improvement Amendments (CLIA) regulations require a facility to be appropriately certified for each test performed. To ensure that Medicare & Medicaid only pay for laboratory tests performed in certified facilities, each claim for a HCPCS code that is considered a CLIA laboratory test is currently edited at the CLIA certificate level.

The CMS Change Request 11765, transmittal 10066, added the "QW modifier to the Healthcare Common Procedure Coding System (HCPCS) code U0002 [2019-nCoV Coronavirus, SARS-CoV-2/2019-nCoV (COVID-19), any technique, multiple types or subtypes (includes all targets), non-CDC], and 87635 [Infectious agent detection by nucleic acid (DNA or RNA); severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]), amplified probe technique]. However, the shared system CWF was not included in the business requirements. This change request adds the shared system CWF to HCPCS codes U0002 and 87635.

This One Time Notification applies to Chapter 16, Section 70.9.

B. Policy: The CLIA regulations require a facility to be appropriately certified for each test performed. To ensure that Medicare and Medicaid only pay for laboratory tests in a facility with a valid, current CLIA certificate, laboratory claims are currently edited at the CLIA certificate level.

II. BUSINESS REQUIREMENTS TABLE

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

Number	Requirement	Responsibility																	
		MAC N				MAC N				MAC 3		MAC M		MAC M		D Shared-M System E Maintainers			Other
		A	В	H H H	M A C	F I	M C S	1	С										
12294.1	The Medicare contractor shall permit the use of code U0002QW for claims submitted by facilities with a valid, current CLIA certificate of waiver with dates of service on or after March 20, 2020.								X										
12294.2	The Medicare contractor shall permit the use of code 87635QW for claims submitted by facilities with a valid current CLIA certificate of waiver with dates of								X										

Number	Requirement	Responsibility								
			A/B	;	D	,	Sha	red-		Other
					Е	Maintainers				
		A	В	Н		F	M	V	C	
				Н	M	_	C	M		
				Н	A	S	S	S	F	
					С	S				
	service on or after March 20, 2020.									
12294.3	Contractors need not search their files to either retract payment for claims already paid or to retroactively pay claims. However, contractors shall adjust claims brought to their attention.		X							

III. PROVIDER EDUCATION TABLE

Number	r Requirement				ility	
		A/B MAC			D M E	C E D
		A	В	H H H	M A C	I
12294.4	MLN Article: CMS will make available an MLN Matters provider education article that will be marketed through the MLN Connects weekly newsletter shortly after the CR is released. MACs shall follow IOM Pub. No. 100-09 Chapter 6, Section 50.2.4.1, instructions for distributing MLN Connects information to providers, posting the article or a direct link to the article on your website, and including the article or a direct link to the article in your bulletin or newsletter. You may supplement MLN Matters articles with localized information benefiting your provider community in billing and administering the Medicare program correctly. Subscribe to the "MLN Matters" listserv to get article release notifications, or review them in the MLN Connects weekly newsletter.		X			

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): Kathleen Todd, kathleen.todd@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: 0