CMS Manual System	**Department of Health & Human Services (DHHS)**
Pub 100-04 Medicare Claims Processing	**Centers for Medicare & Medicaid Services (CMS)**
Transmittal 4227	**Date: February 1, 2019**
	Change Request 11061

SUBJECT: Independent Laboratory Billing of Laboratory Tests for End-Stage Renal Disease (ESRD) Beneficiaries and the Sunset of the CB Modifier

I. SUMMARY OF CHANGES:
This Change Request (CR) sunsets the requirement for independent laboratories to bill separately for ESRD dialysis-related diagnostic tests.

EFFECTIVE DATE: July 1, 2019
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: July 1, 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.*

R/N/D	CHAPTER / SECTION / SUBSECTION / TITLE
R	16/40/6.2.3/Skilled Nursing Facility (SNF) Consolidated Billing (CB) Editing and Separately Billed ESRD Laboratory Test Furnished to Patients of Renal Dialysis Facilities

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:

Business Requirements
Manual Instruction

Attachment - Business Requirements

Pub. 100-04	Transmittal: 4227	Date: February 1, 2019	Change Request: 11061

SUBJECT: Independent Laboratory Billing of Laboratory Tests for End-Stage Renal Disease (ESRD) Beneficiaries and the Sunset of the CB Modifier

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I. GENERAL INFORMATION

A. Background: The Skilled Nursing Facility (SNF) Consolidated Billing (CB) provision requires a SNF to include on its Part A bill almost all of the services that its residents receive during the course of a Part A covered stay. However, there are several categories of services that the law (§1888(e)(2)(A)(ii) of the Social Security Act) specifically excludes from this provision, and these excluded services remain separately billable under Part B by the outside provider or supplier that furnishes them. One of the excluded categories encompasses those items and services that fall within the scope of the Part B benefit that covers chronic dialysis for beneficiaries with ESRD (§1861(s)(2)(F) of the Act).

Prior to January 1, 2011, Medicare paid Independent Laboratories (IL) directly for furnishing diagnostic tests that were ESRD dialysis-related. For purposes of the SNF CB, ESRD dialysis-related was defined as: (1) the beneficiary must be an ESRD beneficiary; (2) the test must have been ordered by an ESRD facility; and (3) the test must relate directly to the dialysis treatment of the beneficiary's ESRD. Therefore, an IL could be paid separately (outside of the SNF CB) for an ESRD dialysis-related diagnostic test furnished to a SNF Part A resident, provided the test was outside the ESRD facility's composite rate when the diagnostic test was billed with the CB modifier – services ordered by a dialysis facility physician as part of the ESRD beneficiary's dialysis benefit, is not part of the composite rate, and is separately reimbursable. Change Request (CR) 2475 implemented the CB modifier and CR 2906 revised the criteria for using the CB modifier.

Section 153(b) of the Medicare Improvements for Patients and Providers Act (MIPPA) required the implementation of the ESRD PPS effective January 1, 2011. The ESRD PPS replaced the basic case-mix adjusted composite payment system and the methodologies for the reimbursement of separately billable outpatient ESRD related items and services. The ESRD PPS provides a single payment to ESRD facilities, i.e., hospital-based providers of services and renal dialysis facilities, that pays for all the resources used in providing an outpatient dialysis treatment, including supplies and equipment used to administer dialysis in the ESRD facility or at a patient's home, drugs, biologicals, laboratory tests, training, and support services.

The ESRD PPS includes consolidated billing requirements for limited Part B services included in the ESRD facility's bundled payment. The Centers for Medicare & Medicaid Services (CMS) periodically update the lists of items and services that are subject to Part B consolidated billing and are therefore no longer separately payable when provided to ESRD beneficiaries by providers other than ESRD facilities. CR 7064 implemented the ESRD PPS consolidated billing requirements, which are discussed on the CMS Website located at this link: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/Consolidated_Billing.html

Since the implementation of the ESRD PPS, ILs are no longer able to bill Medicare directly for any diagnostic test that is related to the treatment of ESRD as payment for the test is already included in the ESRD PPS base rate paid to the ESRD facility. CMS inadvertently did not eliminate the use of the CB

modifier when the ESRD PPS was implemented.

This CR sunsets the requirement for ILs to use the "CB" HCPCS modifier to bill separately for renal dialysis laboratory tests.

B. Policy: Effective January 1, 2011, ILs shall no longer report the CB modifier. All laboratory tests determined to be furnished for the treatment of ESRD are paid in the ESRD facility bundled payment and therefore, may only be reported by the ESRD facility. Therefore, the CB modifier, which is a payment mechanism for ILs to report when requesting separate payment outside the SNF CB for ESRD dialysis-related services, is no longer available.

With the January 1, 2011 implementation of the ESRD PPS and effective for DOS on or after July 1, 2019, Exhibit 1 is no longer recognized as the list of separately billable ESRD dialysis-related services. Instead, a list of the recognized renal dialysis laboratory tests that are subject to Part B ESRD PPS consolidated billing requirements, are considered routinely performed for the treatment of ESRD, and are not separately paid when provided to ESRD beneficiaries by providers or suppliers other than the ESRD facility, is located on the CMS Website: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/Consolidated_Billing.html.

The list of renal dialysis laboratory tests provided in the Part B ESRD PPS consolidated billing requirements is not an all-inclusive list. For laboratory tests not included in this list, the distinction of what is considered to be a renal dialysis laboratory test is a clinical decision determined by the ESRD beneficiary's ordering practitioner. If any laboratory test is ordered for the treatment of ESRD, then the laboratory test is considered to be included in the ESRD PPS, is the responsibility of the ESRD facility and is excluded from the SNF PPS. More information regarding renal dialysis services payable under the ESRD PPS is available in Pub. 100-02, chapter 11.

Beneficiaries in a SNF Part A stay are eligible for a broad range of diagnostic services as part of the SNF Part A benefit. Physicians ordering medically necessary diagnostic tests that are not directly related to the beneficiary's ESRD are subject to the SNF consolidated billing requirements. Physicians may bill the A/B MAC (B) for the professional component of these diagnostic tests. In most cases, however, the technical component of diagnostic tests is included in the SNF PPS rate and is not separately billable to the A/B MAC (B). Physicians should coordinate with the SNF in ordering such tests since the SNF will be responsible for bearing the cost of the technical component.

A patient's physician or practitioner may order a laboratory test that is included on the list of items and services subject to consolidated billing edits for reasons other than for the treatment of ESRD. When this occurs, the SNF CB applies.

NOTE: CMS will ensure that the CB modifier is invalidated as of July 1, 2019.

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	
11061.1	Effective for claims with the Dates of Service (DOS) on and after July 1, 2019, Contractors and Shared		X						X	

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
	System Maintainers shall discontinue/turn off any claims processing edits containing the "CB" modifier.									
11061.2	Contractors shall reject/return as unprocessable/RTP claim details with line item date of service on or after July 1, 2019 that contain the CB modifier.	X	X							
11061.2.1	Contractors shall perform maintenance to end date modifier CB with the term date of 063019 on the HCPCS MODIFIERS INQUIRY screen (6K). Once this maintenance is completed, claims with the CB modifier with a from date on or after 7/1/2019 will RTP with Reason code 31164. 31164 STANDARD NARRATIVE: INVALID LINE ITEM MODIFIER. OR LINE ITEM DATE OF SERVICE IS NOT WITHIN OR EQUAL TO MODIFIER EFFECTIVE AND TERMINATION DATE.	X								
11061.3	Contractors shall use CARC Code 182 - "Procedure modifier was invalid on the date of service." Group Code CO - Contractual Obligation.		X							
11061.4	Contractors shall be aware of, and in compliance with, the updated policy provided with this instruction in publication 100-04, chapter 16, section 40.6.2.3.	X	X							

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility				
		A/B MAC			DME MAC	CEDI
		A	B	HHH		
11061.5	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	X			

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): Michelle Cruse, 410-786-7540 or michelle.cruse@cms.hhs.gov , Vickie Poff, 410-786-0836 or Vickie.Poff1@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

40.6.2.3 - Skilled Nursing Facility (SNF) Consolidated Billing (CB) Editing and Laboratory Tests Furnished to End-Stage Renal Disease (ESRD) Beneficiaries

(Rev.4227, Issued: 02-01-2019, Effective: 07-01-19, Implementation: 07-01-19)

Effective April 1, 2003, for dates of service (DOS) on or after April 1, 2001 and ending June 30, 2019:

Effective April 1, 2003, for DOS on or after April 1, 2001, CWF will not apply the SNF CB edits to line items that contain the CB modifier. A provider or supplier may use the "CB" modifier only when it has determined that: (a) the beneficiary has ESRD entitlement, (b) the test is related to the dialysis treatment for ESRD, (c) the test is ordered by a doctor providing care to patients in the dialysis facility, and (d) the test is not included in the dialysis facility's composite rate payment.

Those diagnostic tests that are presumptively considered to be dialysis-related and, therefore, appropriate for submission with the "CB" modifier are identified in Exhibit 1. This list was not designed as an all- inclusive list of Medicare covered diagnostic services. Additional diagnostic services related to the beneficiary's ESRD treatment/care may be considered dialysis-related. However, if these services are not included in our listing, the A/B MAC (A) may require supporting medical documentation.

When a hospital laboratory is billing for laboratory services ordered by an ESRD facility and the patient (beneficiary) is a SNF resident under a Part A stay, the hospital laboratory must use the "CB" modifier for those services excluded from consolidated billing.

Beneficiaries in a SNF Part A stay are eligible for a broad range of diagnostic services as part of the SNF Part A benefit. Physicians ordering medically necessary diagnostic test that are not directly related to the beneficiary's ESRD are subject to the SNF consolidated billing requirements. Physicians may bill the A/B MAC (B) for the professional component of these diagnostic tests. In most cases, however, the technical component of diagnostic tests is included in the SNF PPS rate and is not separately billable to the A/B MAC (B). Physicians should coordinate with the SNF in ordering such tests since the SNF will be responsible for bearing the cost of the technical component.

Effective for DOS on or after July 1, 2019:

Effective for claims with DOS on or after July 1, 2019, the CB modifier, previously used by Independent Labs when billing for separate payment outside the SNF Consolidated Billing for ESRD dialysis-related lab services, is no longer applicable.

With the January 1, 2011 implementation of the ESRD PPS and effective for DOS on or after July 1, 2019, Exhibit 1 is no longer recognized as the list of separately billable ESRD dialysis-related services. Instead, a list of the recognized renal dialysis laboratory tests that are subject to Part B ESRD PPS consolidated billing requirements, are considered routinely performed for the treatment of ESRD, and are not separately paid when provided to ESRD beneficiaries by providers or suppliers other than the ESRD facility, is located on the CMS Website: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/Consolidated_Billing.html.

The list of renal dialysis laboratory tests provided in the Part B ESRD PPS consolidated billing requirements is not an all-inclusive list. For laboratory tests not included in this list, the distinction of what is considered to be a renal dialysis laboratory test is a clinical decision determined by the ESRD beneficiary's ordering practitioner. If any laboratory test is ordered for the treatment of ESRD, then the laboratory test is considered to be included in the ESRD PPS, is the responsibility of the ESRD facility and is excluded from the SNF PPS. More information regarding renal dialysis services payable under the ESRD PPS is available in Pub. 100-02, chapter 11.

Beneficiaries in a SNF Part A stay are eligible for a broad range of diagnostic services as part of the SNF Part A benefit. Physicians ordering medically necessary diagnostic tests that are not directly related to

the beneficiary's ESRD are subject to the SNF consolidated billing requirements. Physicians may bill the A/B MAC (B) for the professional component of these diagnostic tests. In most cases, however, the technical component of diagnostic tests is included in the SNF PPS rate and is not separately billable to the A/B MAC (B). Physicians should coordinate with the SNF in ordering such tests since the SNF will be responsible for bearing the cost of the technical component.

A patient's physician or practitioner may order a laboratory test that is included on the list of items and services subject to consolidated billing edits for reasons other than for the treatment of ESRD. When this occurs, the SNF CB applies.