CMS Manual System	**Department of Health & Human Services (DHHS)**
Pub 100-04 Medicare Claims Processing	**Centers for Medicare & Medicaid Services (CMS)**
Transmittal 10341	**Date: September 4, 2020**
	Change Request 11935

SUBJECT: Internet Only Manual Update to Pub. 100-04, Chapter 16, Section 60.1.2 and Pub. 100-04, Chapter 26, Section 10.4, Item 19

I. SUMMARY OF CHANGES: This Change Request (CR) removes the reference to EKG services in the claims processing manual, Publication 100-04, Chapter 16, section 60.1.2 and Publication 100-04, Chapter 26, section 10.4, Item 19.

EFFECTIVE DATE: October 6, 2020
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: October 6, 2020

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	16/60/60.1.2/Independent Laboratory Specimen Drawing
R	26/10/10.4/Items 14-33 - Provider of Service or Supplier Information

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: 10341	Date: September 4, 2020	Change Request: 11935

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I. GENERAL INFORMATION

A. Background: The purpose of this Change Request is to revise the claims processing manual, Publication 100-04, Chapter 16, section 60.1.2 and Publication 100-04, Chapter 26, Section 10.4, item 19. These changes are being made to remove the references to EKG services only. No policy, processing, or system changes are anticipated.

B. Policy: This change is intended only to clarify the existing content and no policy, processing, or system changes are anticipated.

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	
11935.1	Contractors shall be in compliance with the updates to CMS Internet Only Manual (IOM) Publication 100-04, Chapter 16- Laboratory Services, subsection 60.1.2.		X							
11935.2	Contractors shall be in compliance with the updates to CMS Internet Only Manual (IOM) Publication 100-04, Chapter 26-Completing and Processing Form CMS-1500 Data Set, subsection 10.4.		X							

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility				
		A/B MAC			DME MAC	CEDI
		A	B	HHH		
11935.3	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

"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): Vickie Poff, 410-786-0836 or vickie.poff1@cms.hhs.gov , Eric Coulson, 410-786-3352 or eric.coulson@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

10.4 - Items 14-33 - Provider of Service or Supplier Information

(*Rev.10341, Issued: 09-04-2020; Effective: 10- 06- 2020; Implementation: 10- 06-2020)*

Item 19 - Enter either a 6-digit (MM | DD | YY) or an 8-digit (MM | DD | CCYY) date patient was last seen and the NPI of his/her attending physician when a physician providing routine foot care submits claims.

NOTE: Effective May 23, 2008, all provider identifiers submitted on the CMS-1500 claim form MUST be in the form of an NPI.

Enter either a 6-digit (MM | DD | YY) or an 8-digit (MM | DD | CCYY) x-ray date for chiropractor services (if an x-ray, rather than a physical examination was the method used to demonstrate the subluxation). By entering an x-ray date and the initiation date for course of chiropractic treatment in item 14, the chiropractor is certifying that all the relevant information requirements (including level of subluxation) of Pub. 100-02, Medicare Benefit Policy Manual, chapter 15, is on file, along with the appropriate x-ray and all are available for A/B MAC (B) review.

Instructions for Not Otherwise Classified (NOC) Codes – Any unlisted services or procedure code. **Note:** When reporting NOC codes, this field must be populated as specified below.

Enter the drug's name and dosage when submitting a claim for NOC drugs.

Enter a concise description of an "unlisted procedure code" or a NOC code if one can be given within the confines of this box. Otherwise an attachment shall be submitted with the claim.

When billing for unlisted laboratory tests using a NOC code, this field **MUST** include the specific name of the laboratory test(s) and/or a short descriptor of the test(s). Claims for unlisted laboratory tests that are received without this information shall be treated according to the requirements found in Pub. 100-04, Medicare Claims Processing Manual, Chapter 1, Section 80.3.2 and “returned as unprocessable.” Section 216(a) of the Protecting Access to Medicare Act of 2014 (PAMA) requires reporting entities to report private payor payment rates for laboratory tests and the corresponding volumes of tests. In compliance with PAMA, CMS must collect private payor data on unique tests currently being paid as a NOC code, Not Otherwise Specified (NOS) code, or unlisted service or procedure code.

Enter all applicable modifiers when modifier -99 (multiple modifiers) is entered in item 24d. If modifier -99 is entered on multiple line items of a single claim form, all applicable modifiers for each line item containing a -99 modifier should be listed as follows: 1=(mod), where the number 1 represents the line item and "mod" represents all modifiers applicable to the referenced line item.

Enter the statement "Homebound" when an independent laboratory obtains a specimen from a homebound or institutionalized patient. (See Pub. 100-02, Medicare Benefit Policy Manual, Chapter 15, "Covered Medical and Other Health Services," and Pub. 100-04, Medicare Claims Processing Manual, Chapter 16, "Laboratory Services,” and Pub. 100-01, Medicare General Information, Eligibility, and Entitlement Manual, Chapter 5, "Definitions," respectively, for the definition of "homebound" and a more complete definition of a medically necessary laboratory service to a homebound or an institutional patient.)

Enter the statement, "Patient refuses to assign benefits," when the beneficiary absolutely refuses to assign benefits to a non-participating physician/supplier who accepts assignment on a claim. In this case, payment can only be made directly to the beneficiary.

Enter the statement, "Testing for hearing aid" when billing services involving the testing of a hearing aid(s) is used to obtain intentional denials when other payers are involved.

When dental examinations are billed, enter the specific surgery for which the exam is being performed.

Enter the specific name and dosage amount when low osmolar contrast material is billed, but only if HCPCS codes do not cover them.

Enter a 6-digit (MM | DD | YY) or an 8-digit (MM | DD | CCYY) assumed and/or relinquished date for a global surgery claim when providers share post-operative care.

Enter demonstration ID number "30" for all national emphysema treatment trial claims.

Enter demonstration ID number “56” for all national Laboratory Affordable Care Act Section 113 Demonstration Claims.

Enter the NPI of the physician who is performing the technical or professional component of a diagnostic test that is subject to the anti-markup payment limitation. (See Pub. 100-04, chapter 1, section 30.2.9 for additional information.)

NOTE: Effective May 23, 2008, all provider identifiers submitted on the CMS-1500 claim form MUST be in the form of an NPI.

Method II suppliers shall enter the most current HCT value for the injection of Aranesp for ESRD beneficiaries on dialysis. (See Pub. 100-04, chapter 8, section 60.7.2.)

Individuals and entities who bill A/B MACs (B) for administrations of ESAs or Part B anti-anemia drugs not self-administered (other than ESAs) in the treatment of cancer must enter the most current hemoglobin or hematocrit test results. The test results shall be entered as follows: TR= test results (backslash), R1=hemoglobin, or R2=hematocrit (backslash), and the most current numeric test result figure up to 3 numerics and a decimal point [xx.x]). Example for hemoglobin tests: TR/R1/9.0, Example for Hematocrit tests: TR/R2/27.0.

60.1.2 - Independent Laboratory Specimen Drawing

(Rev.10341, Issued: 09-04-2020; Effective: 10- 06- 2020; Implementation: 10- 06- 2020)

Medicare allows separate charges made by laboratories for drawing or collecting specimens whether or not the specimens are referred to hospitals or independent laboratories. The laboratory does not bill for routine handling charges where a specimen is referred by one laboratory to another.

Medicare allows payment for a specimen collection fee when it is medically necessary for a laboratory technician to draw a specimen from either a nursing home patient or homebound patient. Payment for the specimen collection fee is made based on the clinical laboratory fee schedule. The technician must personally draw the specimen, e.g., venipuncture or urine sample by catheterization. Medicare does not allow a specimen collection fee to the visiting technician if a patient in a facility is (a) not confined to the facility, or (b) the facility has personnel on duty qualified to perform the specimen collection. Medical necessity for such services exists, for example, where a laboratory technician draws a blood specimen from a homebound or an institutionalized patient. A patient need not be bedridden to be homebound. However, where the specimen is a type that would require only the services of a messenger and would not require the skills of a laboratory technician, e.g., urine or sputum, a specimen pickup service would not be considered medically necessary. (See Chapters 7 and 15 of Pub. 100-02, the Medicare Benefit Policy Manual for a discussion of "homebound" and a more complete definition of a medically necessary laboratory service to a homebound or an institutional patient.)

In addition to the usual information required on claim forms (including the name of the prescribing physician), all independent laboratory claims for such specimen drawing prescribed by a physician should be appropriately annotated, e.g., "patient confined to home," "patient homebound," or "patient in nursing home, no qualified person on duty to draw specimen." A/B MACs (B) must assure the validity of the annotation through scientific claims samples as well as through regular bill review techniques. (This could be done by use of the information in A/B MAC (B) files, and where necessary, contact with the prescribing physician.)

If a physician requests an independent laboratory to obtain specimens in situations which do not meet, or without regard to whether they meet, the medical necessity criteria in Chapter 15 of the Medicare Benefit Policy Manual, an educational contact with the prescribing physician is warranted and, where necessary, corroborating documentation should be obtained on claims until the A/B MAC (B) is assured that the physician prescribes such services only when the criteria are met.

The specimen collection fee is paid based on the location of the independent laboratory where the test is performed and is billed in conjunction with a covered laboratory test.