CMS Manual System	**Department of Health & Human Services (DHHS)**
Pub 100-04 Medicare Claims Processing	**Centers for Medicare & Medicaid Services (CMS)**
Transmittal 4479	**Date: December 20, 2019**
	Change Request 11553

SUBJECT: Internet Only Manual Update to Add New and Revise Sections of Publication 100-04, Chapter 16

I. SUMMARY OF CHANGES: This change request makes updates to chapter 16 of the Medicare Claims Processing Manual.

EFFECTIVE DATE: January 23, 2020
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: January 23, 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	16/20/20/Calculation of Payment Rates - Clinical Laboratory Test Fee Schedules
R	16/20/20.1/Initial Development of Laboratory Fee Schedules
R	16/20/20.2/Annual Fee Schedule Updates
N	16/20/20.3/Clinical Laboratory Fee Schedule Based on Protecting Access to Medicare Act (PAMA) of 2014

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

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I. GENERAL INFORMATION

A. Background: This Change Request (CR) is adding a new section, 20.3 and updating sections 20, 20.1, 20.2 of the Laboratory Services Utilized by Medicare to Chapter 16 in Pub. 100-04, Medicare Claims Processing Manual.

B. Policy: This CR contains no policy changes.

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	
11553.1	The Medicare contractors shall be aware of the manual updates in Publication 100-04, Chapter 16, Section 20, 20.1, 20.2 and new section 20.3.	X	X							

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility				
		A/B MAC			DME MAC	CEDI
		A	B	HHH		
	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): Fred Rooke, Fred.Rooke@cms.hhs.gov , Cindy Pitts, Cindy.Pitts@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

Medicare Claims Processing Manual
Chapter 16 – Laboratory Services

Table of Contents
(Rev.4479; Issued: 12-20-19)

20 - Calculation of Payment Rates - Clinical Laboratory Test Fee Schedules

(Rev.4479; Issued: 12-20-19 Effective: 01-23-20, Implementation: 01-23-20)

Section 216 of Public Law 113-93, the "Protecting Access to Medicare Act of 2014," added section 1834A to the Social Security Act (the Act). This provision requires extensive revisions to the payment and coverage methodologies for clinical laboratory tests paid under the clinical laboratory fee schedule (CLFS). The Centers for Medicare & Medicaid Services (CMS) published CMS-1621-F Medicare Clinical Diagnostic Laboratory Tests Payment System, on June 23, 2016, which implemented the provisions of the new legislation.

The final rule set forth new policies for how CMS sets rates for tests on the CLFS and is effective for dates of service on and after January 1, 2018. Beginning on January 1, 2017, applicable laboratories will be required to submit data to CMS which describes negotiated payment rates with private payers for and corresponding volumes of tests on the CLFS. In general, with certain designated exceptions, the payment amount for a test on the CLFS furnished on or after January 1, 2018, will be equal to the weighted median of private payer rates determined for the test, based on data collected from laboratories during a specified data collection period. In addition, a subset of tests on the CLFS, advanced diagnostic laboratory tests (ADLTs), will have different data, reporting, and payment policies associated with them. In particular, the final rule discusses CMS' proposals regarding:

- *Definition of "applicable laboratory" (who must report data under section 1834A of the Act)*
- *Definition of "applicable information" (what data will be reported)*
- *Data collection period*
- *Schedule for reporting data to CMS*
- *Definition of ADLT*
- *Data Integrity*
- *Confidentiality and public release of limited data*
- *Coding for new tests on the CLFS*
- *Phased in payment reduction*

Prior to January 1, 2018

Under Part B, for services rendered on or after July 1, 1984, clinical laboratory tests performed in a physician's office, by an independent laboratory, or by a hospital laboratory for its outpatients are reimbursed on the basis of fee schedules. Current exceptions to this rule are CAH laboratory services as described in §10, and services provided by hospitals in the State of Maryland.
Medicare pays the lesser of:

- Actual charges;
- The fee schedule amount for the State or a local geographic area; or
- A national limitation amount (NLA) for the HCPCS code as provided by §1834(h) of the Act.

Annually, CMS furnishes to A/B MACs (A) and (B) the proper amount to pay for each HCPCS code for each local geographic area.
This includes a calculation of whether a national limitation amount or the local fee schedule amount is to be used. This information is available to the public on the CMS Web site in public use files.

20.1 - Initial Development of Laboratory Fee Schedules

(Rev.4479; Issued: 12-20-19 Effective: 01-23-20, Implementation: 01-23-20)

Initially, each A/B MAC (B) established the fee schedules on an A/B MAC (B)-wide basis (not to exceed a statewide basis). If an A/B MAC (B)'s area includes more than one State, the A/B MAC (B) established a separate fee schedule for each State. The A/B MAC (B) determined the fee schedule amount based on prevailing charges for laboratory billings by physicians and independent laboratories billing the A/B MAC (B). A/B MACs (B) set the fees at 60 percent of prevailing charges. A/B MACs (A) used the same fee schedules to pay outpatient hospital laboratory services. They set the fee at 62 percent of A/B MAC (B) prevailing charges. Subsequently, except for sole community hospitals, which continue to be paid at the 62 percent rate, A/B MACs (A) changed payments to hospital laboratories to the "60 percent fee schedule."

In 1994, CMS took over the annual update and distribution of clinical laboratory fee schedules. The CMS updates the fee schedule amounts annually to reflect changes in the Consumer Price Index (CPI) for all Urban Consumers (U.S. city average), or as otherwise specified by legislation.

Effective for hospital outpatient tests furnished by a hospital on or after April 1, 1988, to receive the 62 percent fee the hospital must be a sole community hospital. Otherwise, the fee is the "60 percent fee schedule." If a hospital is uncertain whether it meets the qualifications of a sole community hospital it can seek assistance from the A/B MAC (A) or the RO.

For tests to hospital non-patients, the fee is 60 percent of the A/B MAC (B) prevailing charge. If a hospital laboratory acts as an independent laboratory, i.e., performs tests for persons who are nonhospital patients; or if the hospital laboratory is not a qualified hospital laboratory, the services are reimbursed using the 60 percent fee schedule or the adjusted fee schedule, as appropriate.
See §10.1 for the definition of a hospital outpatient.
See §20.3 for CLFS effective January 1, 2018.

20.2 - Annual Fee Schedule Updates

(Rev.4479; Issued: 12-20-19 Effective: 01-23-20, Implementation: 01-23-20)

The CMS adjusts the fee schedule amounts annually to reflect changes in the Consumer Price Index for all urban consumers (CPI-U) (U.S. city average) and the 10-year moving average of changes in annual economy-wide private nonfarm business multi-factor productivity, unless alternative updates are specified by legislation. The CMS communicates this information via an annual recurring update notification (RUN). The CMS also determines, publishes for A/B MAC (A) or (B) use, and places on its web site, coding and pricing changes. This information is updated on an annual basis.
See §20.3 for CLFS effective January 1, 2018.

20.3 – Clinical Laboratory Fee Schedule Based on Protecting Access to Medicare Act (PAMA) of 2014

(Rev.4479; Issued: 12-20-19 Effective: 01-23-20, Implementation: 01-23-20)

Effective January 1, 2018, CLFS rates were based on weighted median private payer rates as required by the Protecting Access to Medicare Act (PAMA) of 2014.

Fee Schedule Through December 31, 2017
Outpatient clinical laboratory services are paid based on a fee schedule in accordance with Section 1833 (h) of the Social Security Act. Payment is lesser of the amount billed, the local fee for a geographic area, or a national limit. In accordance with the statute, the national limits are set at a percent of the median of all local fee schedule amounts for each laboratory test code. Each year, fees are updated for inflation based on

the percentage change in the Consumer Price Index. However, legislation by Congress can modify the update to the fees. Co-payments and deductibles do not apply to services paid under the Medicare clinical laboratory fee schedule.

Each year, new laboratory test codes are added to the clinical laboratory fee schedule and corresponding fees are developed in response to a public comment process. Also, for a cervical or vaginal smear test (pap smear), the fee cannot be less than a national minimum payment amount, initially established at $14.60 and updated each year for inflation.

Sole Community Hospitals
Effective for hospital outpatient tests furnished by a hospital on or after April 1, 1988 through December 31, 2017, to receive the 62 percent fee the hospital must be a sole community hospital. Effective for hospital outpatient tests furnished by a Sole community possessive hospital's payment is based on a fee schedule in accordance with Section 1833(h) of the Social Security Act. Payment is the lesser of the amount billed, the local fee for a geographic area, or a national limit.

Critical Access Hospitals
Critical access hospitals are generally paid for outpatient laboratory tests on a reasonable cost basis, instead of by the fee schedule, as long as the lab service is provided to a CAH outpatient.