

<b>CMS Manual System</b>	<b>Department of Health &amp; Human Services (DHHS)</b>
<b>Pub 100-04 Medicare Claims Processing</b>	<b>Centers for Medicare &amp; Medicaid Services (CMS)</b>
<b>Transmittal 3056</b>	<b>Date: August 29, 2014</b>
	<b>Change Request 8837</b>

**SUBJECT: Sample Collection Fee Adjustment for Clinical Laboratory Fee Schedule and Laboratory Services**

**I. SUMMARY OF CHANGES:** This Change Request (CR) provides instructions for adjusting payment for a sample collected from an individual in a skilled nursing facility or by a laboratory on behalf of a home health agency. This CR applies to Section 1833(h)(3)(A) of the Act, as amended by Section 216 of the Protecting Access to Medicare Act (P.L. 113-93), and Chapter 16, Section 60.1 of the IOM.

**EFFECTIVE DATE: April 1, 2014**

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

**IMPLEMENTATION DATE: December 1, 2014**

*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.*

<b>R/N/D</b>	<b>CHAPTER / SECTION / SUBSECTION / TITLE</b>
R	16/60.1.2/Independent Laboratory Specimen Drawing
R	16/60.1.3/Specimen Drawing for Dialysis Patients
R	16/60.1.4/Coding Requirements for Specimen Collection

**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 obliged 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**



Number	Requirement	Responsibility								
		A/B MAC			D M E M A C	Shared-System Maintainers				Other
		A	B	H H H		F I S S	M C S	V M S	C W F	
	CMS mainframe on or after July 31, 2014.									
8837.3	Contractors shall notify CMS of successful receipt, loading, and implementation via e-mail to price_file_receipt@cms.hhs.gov stating the name of the file received and the entity for which it was received.	X	X							
8837.4	Contractors shall not search their files to either retract payment or retroactively pay claims; however, contractors should adjust claims if they are brought to their attention.	X	X							

### III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility				
		A/B MAC			D M E M A C	C E D I
		A	B	H H H		
8837.5	MLN Article : A provider education article related to this instruction will be available at <a href="http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/">http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/</a> shortly after the CR is released. You will receive notification of the article release via the established "MLN Matters" listserv. Contractors shall post this article, or a direct link to this article, on their Web sites and include information about it in a listserv message within one week of the availability of the provider education article. In addition, the provider education article shall be included in the contractor's next regularly scheduled bulletin. Contractors are free to supplement MLN Matters articles with localized information that would benefit their provider community in billing and administering the Medicare program correctly.	X	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):** Glenn McGuirk, 410-786-5723 or Glenn.McGuirk@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**

## **60.1.2 - Independent Laboratory Specimen Drawing**

**(Rev.3056, Issued: 08-29-14, Effective: 04-01-14, Implementation: 12-01-14)**

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 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. 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 not confined to the facility. 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 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 or EKG services 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.” Carriers 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 carrier 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 carrier is assured that the physician prescribes such services only when the criteria are met.

## **60.1.3 - Specimen Drawing for Dialysis Patients**

**Rev.3056, Issued: 08-29-14, Effective: 04-01-14, Implementation: 12-01-14)**

See the Medicare Benefit Policy Manual, Chapter 11, for a description of laboratory services included in the composite rate. With the implementation of the ESRD PPS, effective for claims with dates of service on or after January 1, 2011, all ESRD-related laboratory services are included in the ESRD PPS base rate.

Clinical laboratory tests can be performed individually or in predetermined groups on automated profile equipment. A specimen collection fee determined by CMS will be allowed only in the following circumstances:

- Drawing a blood sample through venipuncture (i.e., inserting into a vein a needle with a syringe or vacutainer to draw the specimen).
- Collecting a urine sample by catheterization.

Special rules apply when such services are furnished to dialysis patients. The specimen collection fee is not separately payable for patients dialyzed in the facility or for patients dialyzed at home under reimbursement Method I. A specimen collection fee is also not separately payable when an ESRD facility is collecting a specimen for transplant eligibility or other transplant requirements. Payment for specimen collection is included under the ESRD PPS, regardless of whether the laboratory test itself is included in the ESRD PPS or is separately billable with the AY modifier (see §40.6 of this chapter).

Fees for taking specimens in the hospital setting, but outside of the dialysis unit, for use in performing laboratory tests not included in the ESRD composite rate may be paid separately.

## **60.1.4 - Coding Requirements for Specimen Collection**

**Rev.3056, Issued: 08-29-14, Effective: 04-01-14, Implementation: 12-01-14)**

The following HCPCS codes and terminology must be used:

- 36415 – Collection of venous blood by venipuncture.
- G0471 – Collection of venous blood by venipuncture or urine sample by catheterization from an individual in a skilled nursing facility (SNF) or by a laboratory on behalf of a home health agency (HHA)
- P9615 – Catheterization for collection of specimen(s).

The allowed amount for specimen collection in each of the above circumstances is included in the laboratory fee schedule distributed annually by CMS.