

<b>CMS Guidance Document</b>	<b>Department of Health &amp; Human Services (DHHS)</b>
<b>Pub 100-02 Medicare Benefit Policy</b>	<b>Centers for Medicare &amp; Medicaid Services (CMS)</b>
<b>Executive Guidance Number 0078</b>	<b>Date: October 3, 2007</b>
<b>Planned Web Site Address <a href="http://www.cms.hhs.gov/manuals/">http://www.cms.hhs.gov/manuals/</a></b>	<b>Planned Release: 10-18-07</b>

**PROGRAM AREA: Hospital and Ambulatory Policy Group**

**SUBJECT: Requirements for Ordering and Following Orders for Diagnostic Tests**

**APPLIES TO: Independent Diagnostic Testing Facilities, Clinical Diagnostic Laboratories, Physicians and Non-Physician Practitioners**

**I. SUMMARY OF DOCUMENT:** This revision incorporates language inadvertently omitted from section 15021 of the Medicare Carriers Manual when the Internet Only Manual was published.

**II. CHANGES IN POLICY INSTRUCTIONS: (If not applicable, indicate N/A)**

STATUS: R=REVISED, N=NEW, D=DELETED.

<b>Status</b>	<b>CHAPTER/SECTION/SUBSECTION/TITLE</b>
<b>R</b>	15/Table of Contents
<b>R</b>	15/80.1/Clinical Laboratory Services
<b>N</b>	15/80.6/Requirements for Ordering and Following Orders for Diagnostic Tests
<b>N</b>	15/80.6.1/Definitions
<b>N</b>	15/80.6.2/Treating Physician/Practitioner Ordering of Diagnostic Tests
<b>N</b>	15/80.6.3/Interpreting Physician Determines a Different Diagnostic Test is Appropriate
<b>N</b>	15/80.6.4/Rules for Testing Facility to Furnish Additional Tests
<b>N</b>	15/80.6.5/Rules for Testing Facility Interpreting Physician to Furnish Different or Additional Tests

**III. CLEARANCES:**

Clearance & Point of Contact (POC)	Name/Telephone/Component
Senior Official Clearance	Liz Richter/(410)-786-4164/CMM
Agency POC	Roberta Epps/(410) 786-4503/CMM/HAPG/DPS

**IV. TYPE (Check appropriate boxes for type of guidance)**

<input type="checkbox"/>	<b>Audit Guide</b>
<input checked="" type="checkbox"/>	<b>Change Request</b>
<input type="checkbox"/>	<b>HPMS</b>
<input type="checkbox"/>	<b>Joint Signature Memorandum/Technical Director Letter</b>
<input type="checkbox"/>	<b>Manual Transmittal/Non-Change Request</b>

	<b>State Medicaid Director Letters</b>
	<b>Other</b>

**V. STATUTORY OR REGULATORY AUTHORITY: CLIA**

# Attachment - Business Requirements

Pub. 100-02	Transmittal:	Date:	Change Request: 5743
-------------	--------------	-------	----------------------

**SUBJECT: Requirements for Ordering and Following Orders for Diagnostic Tests**

**Effective Date: January 1, 2003**

**Implementation Date: 30 days after issuance**

## I. GENERAL INFORMATION

**A. Background:** The information in this change request incorporates language that was previously contained in section 15021 of the Medicare Carriers Manual that was inadvertently omitted when the Internet Only Manual was published.

**B. Policy:** In order that payment can be made for diagnostic tests, there are certain ordering requirements which must be met. The requirements for both ordering and following orders for diagnostic tests are specified in this change request.

## II. BUSINESS REQUIREMENTS TABLE

*Use "Shall" to denote a mandatory requirement*

Number	Requirement	Responsibility (place an "X" in each applicable column)											
		A / B  M A C	D M  M A C	F I	C A R R I E R	D M E R C	R H I	Shared-System Maintainers				OTHER	
								F I S S	M C S	V M S	C W F		
5743.1	Contractors shall be aware of Pub. 100-02, Chapter 15, Sections 80.6 – 80.6.6 of the Internet Only Manual.	X		X	X								

## III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility (place an "X" in each applicable column)											
		A / B  M A C	D M  M A C	F I	C A R R I E R	D M E R C	R H I	Shared-System Maintainers				OTHER	
								F I S S	M C S	V M S	C W F		
	None.	X		X	X								

## IV. SUPPORTING INFORMATION

A. N/A

## **V. CONTACTS**

**Pre-Implementation Contact(s): Roberta Epps** [Roberta.Epps@cms.hhs.gov](mailto:Roberta.Epps@cms.hhs.gov)

**Post-Implementation Contact(s): Regional Offices**

## **VI. FUNDING**

### **A. For *Fiscal Intermediaries and Carriers*:**

No additional funding will be provided by CMS; contractor activities are to be carried out within their operating budgets.

### **B. For *Medicare Administrative Contractors (MACs)*:**

The contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the Statement of Work (SOW). 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.

# Medicare Benefit Policy Manual

## Chapter 15 – Covered Medical and Other Health Services

---

### Table of Contents

*80.6 - Requirements for Ordering and Following Orders for Diagnostic Tests*

*80.6.1 - Definitions*

*80.6.2 - Treating Physician/Practitioner Ordering of Diagnostic Tests*

*80.6.3 - Interpreting Physician Determines a Different Diagnostic Test is Appropriate*

*80.6.4 - Rules for Testing Facility to Furnish Additional Tests*

*80.6.5 - Rules for Testing Facility Interpreting Physician to Furnish Different or Additional Tests*

*80.6.6 - Surgical/Cytopathology Exception*

## **80.1 - Clinical Laboratory Services**

*(Rev.)*

Section [1833](#) and [1861](#) of the Act provides for payment of clinical laboratory services under Medicare Part B. Clinical laboratory services involve the biological, microbiological, serological, chemical, immunohematological, hematological, biophysical, cytological, pathological, or other examination of materials derived from the human body for the diagnosis, prevention, or treatment of a disease or assessment of a medical condition. Laboratory services must meet all applicable requirements of the Clinical Laboratory Improvement Amendments of 1988 (CLIA), as set forth at 42 CFR part 493. Section [1862\(a\)\(1\)\(A\)](#) of the Act provides that Medicare payment may not be made for services that are not reasonable and necessary. Clinical laboratory services must be ordered and used promptly by the physician who is treating the beneficiary as described in [42 CFR 410.32\(a\)](#), or by a qualified nonphysician practitioner, as described in 42 CFR 410.32(a)(3).

*See section 80.6 of this manual for related physician ordering instructions.*

See the Medicare Claims Processing Manual Chapter 16 for related claims processing instructions.

## **80.6 - Requirements for Ordering and Following Orders for Diagnostic Tests**

*(Rev.)*

*The following sections provide instructions about ordering diagnostic tests and for complying with such orders for Medicare payment.*

*NOTE: Unless specified, these sections are not applicable in a hospital setting.*

### **80.6.1 - Definitions**

*(Rev.)*

#### **Diagnostic Test**

*A “diagnostic test” includes all diagnostic x-ray tests, all diagnostic laboratory tests, and other diagnostic tests furnished to a beneficiary.*

#### **Treating Physician**

*A “treating physician” is a physician, as defined in §1861(r) of the Social Security Act (the Act), who furnishes a consultation or treats a beneficiary for a specific medical problem, and who uses the results of a diagnostic test in the management of the beneficiary’s specific medical problem.*

*A radiologist performing a therapeutic interventional procedure is considered a treating physician. A radiologist performing a diagnostic interventional or diagnostic procedure is not considered a treating physician.*

### ***Treating Practitioner***

*A “treating practitioner” is a nurse practitioner, clinical nurse specialist, or physician assistant, as defined in §1861(s)(2)(K) of the Act, who furnishes, pursuant to State law, a consultation or treats a beneficiary for a specific medical problem, and who uses the result of a diagnostic test in the management of the beneficiary’s specific medical problem.*

### ***Testing Facility***

*A “testing facility” is a Medicare provider or supplier that furnishes diagnostic tests. A testing facility may include a physician or a group of physicians (e.g., radiologist, pathologist), a laboratory, or an independent diagnostic testing facility (IDTF).*

### ***Order***

*An “order” is a communication from the treating physician/practitioner requesting that a diagnostic test be performed for a beneficiary. The order may conditionally request an additional diagnostic test for a particular beneficiary if the result of the initial diagnostic test ordered yields to a certain value determined by the treating physician/practitioner (e.g., if test X is negative, then perform test Y). An order may be delivered via the following forms of communication:*

- A written document signed by the treating physician/practitioner, which is hand-delivered, mailed, or faxed to the testing facility;*
- A telephone call by the treating physician/practitioner or his/her office to the testing facility; and*
- An electronic mail by the treating physician/practitioner or his/her office to the testing facility.*

*If the order is communicated via telephone, both the treating physician/practitioner or his/her office, and the testing facility must document the telephone call in their respective copies of the beneficiary’s medical records.*

## ***80.6.2 - Treating Physician/Practitioner Ordering of Diagnostic Tests (Rev.)***

*The treating physician/practitioner must order all diagnostic tests. For a test to be reasonable and necessary, it must be both ordered by the physician and the ordering physician must use the result in the management of the beneficiary’s specific medical*

*problem. A standing order is not sufficient to order clinical diagnostic laboratory tests payable under the Medicare Part B clinical laboratory fee schedule including orders for routine blood glucose monitoring. A testing facility that furnishes a diagnostic test ordered by the treating physician/practitioner may not change the diagnostic test or perform an additional diagnostic test without a new order.*

### ***80.6.3 - Interpreting Physician Determines a Different Diagnostic Test is Appropriate*** ***(Rev.)***

*When an interpreting physician, e.g., radiologist, cardiologist, family practitioner, general internist, neurologist, obstetrician, gynecologist, ophthalmologist, thoracic surgeon, vascular surgeon, at a testing facility determines that an ordered diagnostic radiology test is clinically inappropriate or suboptimal, and that a different diagnostic test should be performed (e.g., an MRI should be performed instead of a CT scan because of the clinical indication), the interpreting physician/testing facility may not perform the unordered test until a new order from the treating physician/practitioner has been received. Similarly, if the result of an ordered diagnostic test is normal and the interpreting physician believes that another diagnostic test should be performed (e.g., a renal sonogram was normal and based on the clinical indication, the interpreting physician believes an MRI will reveal the diagnosis), an order from the treating physician must be received prior to performing the unordered diagnostic test.*

### ***80.6.4 - Rules for Testing Facility to Furnish Additional Tests*** ***(Rev.)***

*If the testing facility cannot reach the treating physician/practitioner to change the order or obtain a new order and documents this in the medical record, then the testing facility may furnish the additional diagnostic test if all of the following criteria apply:*

- The testing center performs the diagnostic test ordered by the treating physician/practitioner;*
- The interpreting physician at the testing facility determines and documents that, because of the abnormal result of the diagnostic test performed, an additional diagnostic test is medically necessary;*
- Delaying the performance of the additional diagnostic test would have an adverse effect on the care of the beneficiary;*
- The result of the test is communicated to and is used by the treating physician/practitioner in the treatment of the beneficiary; and*
- The interpreting physician at the testing facility documents in his/her report why additional testing was done.*



**EXAMPLE:**

*The last cut of an abdominal CT scan with contrast shows a mass requiring a pelvic CT scan to further delineate the mass; (b) a bone scan reveals a lesion on the femur requiring plain films to make a diagnosis.*

**80.6.5 - Rules for Testing Facility Interpreting Physician to Furnish Different or Additional Tests  
(Rev.)**

*The following applies to an interpreting physician of a testing facility who furnishes a diagnostic test to a beneficiary who is not a hospital inpatient or outpatient. The interpreting physician must document accordingly in his/her report to the treating physician/practitioner.*

**Test Design**

*Unless specified in the order, the interpreting physician may determine, without notifying the treating physician/practitioner, the parameters of the diagnostic test (e.g., number of radiographic views obtained, thickness of tomographic sections acquired, use or non-use of contrast media).*

**Clear Error**

*The interpreting physician may modify, without notifying the treating physician/practitioner, an order with clear and obvious errors that would be apparent to a reasonable layperson, such as the patient receiving the test (e.g., x-ray of wrong foot ordered).*

**Patient Condition**

*The interpreting physician may cancel, without notifying the treating physician/practitioner, an order because the beneficiary's physical condition at the time of diagnostic testing will not permit performance of the test (e.g., a barium enema cannot be performed because of residual stool in colon on scout KUB; 170.5PA/LAT of the chest cannot be performed because the patient is unable to stand). When an ordered diagnostic test is cancelled, any medically necessary preliminary or scout testing performed is payable.*

**80.6.6 - Surgical/Cytopathology Exception  
(Rev.)**

*This exception applies to an independent laboratory's pathologist or a hospital pathologist who furnishes a pathology service to a beneficiary who is not a hospital inpatient or outpatient, and where the treating physician/practitioner does not specifically request additional tests the pathologist may need to perform. When a*

*surgical or cytopathology specimen is sent to the pathology laboratory, it typically comes in a labeled container with a requisition form that reveals the patient demographics, the name of the physician/practitioner, and a clinical impression and/or brief history. There is no specific order from the surgeon or the treating physician/practitioner for a certain type of pathology service. While the pathologist will generally perform some type of examination or interpretation on the cells or tissue, there may be additional tests, such as special stains, that the pathologist may need to perform, even though they have not been specifically requested by the treating physician/practitioner. The pathologist may perform such additional tests under the following circumstances:*

- These services are medically necessary so that a complete and accurate diagnosis can be reported to the treating physician/practitioner;*
- The results of the tests are communicated to and are used by the treating physician/practitioner in the treatment of the beneficiary; and*
- The pathologist documents in his/her report why additional testing was done.*

***EXAMPLE:***

*A lung biopsy is sent by the surgeon to the pathology department, and the pathologist finds a granuloma which is suspicious for tuberculosis. The pathologist cultures the granuloma, sends it to bacteriology, and requests smears for acid fast bacilli (tuberculosis). The pathologist is expected to determine the need for these studies so that the surgical pathology examination and interpretation can be completed and the definitive diagnosis reported to the treating physician for use in treating the beneficiary.*