

CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-02 Medicare Benefit Policy	Centers for Medicare & Medicaid Services (CMS)
Transmittal 82	Date: FEBRUARY 8, 2008
	Change Request 5946

Subject: January 2008 Update of the Hospital Outpatient Prospective Payment System (OPPS)-Manualization

I. SUMMARY OF CHANGES: This Recurring Update Notification updates the Medicare Benefit Policy Manual, Pub.100-02, Chapter 6, sections 20 through 20.6 and 70.5. to clarify the existing policy.

New/Revised Material

Effective Date: January 1, 2008

Implementation Date: March 10, 2008

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

R/N/D	CHAPTER/SECTION/SUBSECTION/TITLE
R	6/Table of Contents
R	6/20/Outpatient Hospital Services
R	6/20.1/Limitations on Coverage of Certain Services Furnished to Hospital Outpatients
N	6/20.1.1/General Rule
N	6/20.1.2/Exception to Limitation
R	6/20.2/Outpatient Defined
R	6/20.3/Encounter Defined
D	6/20.3.1/Diagnostic Services Defined
D	6/20.3.2/Coverage of Outpatient Diagnostic Services
D	6/20.3.3/Outpatient Diagnostic Services Under Arrangements
R	6/20.4/Outpatient Diagnostic Services
R	6/20.4.1/Diagnostic Services Defined

N	6/20.4.4/Coverage of Outpatient Diagnostic Services
N	6/20.4.5/Outpatient Diagnostic Services Under Arrangements
R	6/20.5/Outpatient Therapeutic Services
N	6/20.5.1/Coverage of Outpatient Therapeutic Services Incident to a Physicians Service Furnished on or After August 1, 2000
N	6/20.6/Outpatient Observation Services
R	6/70.5/Laboratory Services Furnished to Nonhospital Patients by Hospital Laboratory

III. FUNDING:

SECTION 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.

SECTION B: 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:

Manual Instruction

Recurring Update Notification

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

Attachment – Recurring Update Notification

Pub. 100-02	Transmittal: 82	Date: February 8, 2008	Change Request: 5946
-------------	-----------------	------------------------	----------------------

SUBJECT: January 2008 Update of the Hospital Outpatient Prospective Payment System (OPPS)-Manualization

Effective Date: January 1, 2008
Implementation Date: March 10, 2008

I. GENERAL INFORMATION

A. Background: This Recurring Update Notification updates sections 20 through 20.6 and 70.5 of Chapter 6 of the Medicare Benefits Policy Manual, Pub.100-02, to clarify the existing policy.

B. Policy: Refer to the Medicare Benefits Policy Manual, Pub.100-02, Chapter 6, sections 20 through 20.6 and 70.5 for the latest revisions.

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 E M A C	F I	C A R R I E R	R H I	Shared-System Maintainers			
						F I S S	M C S	V M S	C W F	
5946.1	Medicare Contractors shall refer to the Medicare Benefits Policy Manual, Pub.100-02, Chapter 6, sections 20 through 20.6 and 70.5 for the latest revisions.	X		X		X				

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility (place an "X" in each applicable column)								
		A / B M A C	D M E M A C	F I	C A R R I E R	R H H I	Shared-System Maintainers			
						F I S S	M C S	V M S	C W F	
5946.2	<p>A provider education article related to this instruction will be available at http://www.cms.hhs.gov/MLNMattersArticles/ shortly after the CR is released. You will receive notification of the article release via the established "MLN Matters" listserv.</p> <p>Contractors shall post this article, or a direct link to this article, on their Web site and include information about it in a listserv message within 1 week of the availability of the provider education article. In addition, the provider education article shall be included in your 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.</p>	X		X		X				

IV. SUPPORTING INFORMATION

Section A: For any recommendations and supporting information associated with listed requirements, use the box below:

Use "Should" to denote a recommendation.

X-Ref Requirement Number	Recommendations or other supporting information:
CR 5912	January 2008 Update of the Hospital Outpatient Prospective Payment System (OPPS)

Section B: For all other recommendations and supporting information, use this space:

V. CONTACTS

Pre-Implementation Contact(s): Marina Kushnirova at marina.kushnirova@cms.hhs.gov

Post-Implementation Contact(s): Regional Office

VI. FUNDING

Section A: For *Fiscal Intermediaries (FIs), Carriers, and Regional Home Health Carriers (RHHIs)*:

Medicare Benefit Policy Manual

Chapter 6 - Hospital Services Covered Under Part B

Table of Contents *(Rev. 82, 02-08-08)*

- 20.1 - *Limitation on Coverage of Certain Services Furnished to Hospital Outpatients*
 - 20.1.1 *General Rule*
 - 20.1.2 *Exception to Limitation*
- 20.2 - *Outpatient Defined*
- 20.3 - *Encounter Defined*
- 20.4 - *Outpatient Diagnostic Services*
 - 20.4.1 - *Diagnostic Services Defined*
 - 20.4.4 - *Coverage of Outpatient Diagnostic Services*
 - 20.4.5 - *Outpatient Diagnostic Services Under Arrangements*
- 20.5 - *Outpatient Therapeutic Services*
 - 20.5.1 - *Coverage of Outpatient Therapeutic Services Incident to a Physician's Service Furnished on or After August 1, 2000*
- 20.6 - *Outpatient Observation Services*

20 - Outpatient Hospital Services

(Rev. 82; Issued: 02-08-08; Effective: 01-01-08; Implementation: 03-10-08)

Hospitals provide two distinct types of services to outpatients: services that are diagnostic in nature, and other services that aid the physician in the treatment of the patient. Part B covers both the diagnostic and the therapeutic services furnished by hospitals to outpatients. The following rules pertaining to the coverage of outpatient hospital services are not applicable to physical therapy, speech-language pathology, occupational therapy, or end stage renal disease (ESRD) services furnished by hospitals to outpatients.

- See the Medicare Benefit Policy Manual, *Pub. 100-02*, Chapter 15, "Covered Medical and Other Health Services," sections 220 and 230, for rules on the coverage of outpatient physical therapy, occupational therapy and speech-language pathology furnished by a hospital.
- *See the Medicare Benefit Policy Manual, Pub.100-02, Chapter 11, "End Stage Renal Disease (ESRD)" for rules on the coverage of ESRD services.*
- *For policies specific to partial hospitalization services, see the Medicare Benefit Policy Manual, Pub. 100-02, chapter 6, section 70.3, and the Medicare Claims Processing Manual, Pub. 100-04, chapter 4, section 260.*
- *For rules on the coverage of medical and other health services that are separate Medicare Part B benefits and, therefore, not covered as incident to the services of a physician, see the Medicare Benefit Policy Manual, Pub.100-02, Chapter 15, "Covered Medical and Other Health Services," section 60.*
- *For rules on the coverage of services and supplies furnished incident to a physician's professional services in an office or physician-directed clinic setting, refer to the Medicare Benefit Policy Manual, Pub. 100-02, Chapter 15, "Covered Medical and Other Health Services," section 60.*

20.1 - Limitations on Coverage of Certain Services Furnished to Hospital Outpatients

(Rev. 82; Issued: 02-08-08; Effective: 01-01-08; Implementation: 03-10-08)

Sources: 42 CFR 410.42(a) and 64 FR 18536, April 7, 2000

20.1.1 - General Rule

(Rev. 82; Issued: 02-08-08; Effective: 01-01-08; Implementation: 03-10-08)

Except as provided in section 20.1.2 of this chapter, Medicare Part B does not pay for any item or service that is furnished to a hospital outpatient, as defined in section 20.2, during an encounter, as defined in section 20.3, by an entity other than the hospital unless the hospital has arrangements with that entity to furnish that particular service to its patients. The arrangements must provide that Medicare payment made to the hospital

that arranged for the services discharges the liability of the beneficiary or any other person to pay for those services. See the Medicare General Information, Eligibility, and Entitlement Manual, Pub.100-01, chapter 5, section 10.3 for the definition of “arrangements.” For the purposes of this section, the term “hospital” includes a Critical Access Hospital (CAH).

20.1.2 - Exception to Limitation

(Rev. 82; Issued: 02-08-08; Effective: 01-01-08; Implementation: 03-10-08)

The limitation stated in section 20.1.1 does not apply to the following services:

- *Physicians’ professional services that meet the following conditions:*
 - *The services are personally furnished for an individual beneficiary by a physician;*
 - *The services contribute directly to the diagnosis or treatment of an individual beneficiary;*
 - *The services ordinarily require performance by a physician;*
 - *In the case of radiology or laboratory services, additional requirements in 42 CFR §415.120 and §415.130, respectively of the Code of Federal Regulations are met.*
- *Physician assistant services, as defined in section 1861(s)(2)(K)(i) of the Social Security Act (the Act);*
- *Nurse practitioner and clinical nurse specialist services, as defined in section 1861(s)(2)(K)(ii) of the Act;*
- *Qualified psychologist services, as defined in section 1861(ii) of the Act;*
- *Services of an anesthetist, as defined in regulations in 42 CFR 410.69;*
- *Services furnished to SNF residents as defined in regulations in 42 CFR 411.15(p).*

20.2 - Outpatient Defined

(Rev. 82; Issued: 02-08-08; Effective: 01-01-08; Implementation: 03-10-08)

A hospital outpatient is a person who has not been admitted by the hospital as an inpatient but is registered on the hospital records as an outpatient and receives services (rather than supplies alone) from the hospital *or CAH*. Where a tissue sample, blood sample, or specimen is taken by personnel that are neither employed nor arranged for by the hospital and is sent to the hospital for performance of tests, the tests are not outpatient

hospital services since the patient does not directly receive services from the hospital. See section 70.5 for coverage of laboratory services furnished to nonhospital patients by a hospital laboratory *unless the patient is also a registered hospital outpatient receiving outpatient services from the hospital on the same day and the hospital is not a CAH or Maryland waiver hospital*. Similarly, supplies provided by a hospital supply room for use by physicians in the treatment of private patients are not covered as an outpatient service since the patients receiving the supplies are not outpatients of the hospital. (See the Medicare Benefit Policy Manual, *Pub. 100-02*, Chapter 1, “Inpatient Hospital Services,” section 10, for the definition of “inpatient.”)

Where the hospital uses the category "day patient," i.e., an individual who receives hospital services during the day and is not expected to be lodged in the hospital at midnight, the individual is considered an outpatient. For information on outpatient observation status, refer to *section 20.6 of this chapter and* to the Medicare Claims Processing Manual, *Pub.100-04*, chapter 4, *section 290*, “*Outpatient Observation Services*.” *For information on conditions when an inpatient admission may be changed to outpatient status, refer to the Medicare Claims Processing Manual, Pub.100-04, Chapter 1, “General Billing Requirements,” section 50.3.*

The inpatient of a SNF may be considered the outpatient of a participating hospital. However, the inpatient of a participating hospital cannot be considered an outpatient of that or any other hospital.

Outpatient hospital services furnished in the emergency room to a patient classified as “dead on arrival” are covered *until* pronouncement of death, if the hospital considers such patients as outpatients for record-keeping purposes and follows its usual outpatient billing practice for such services to all patients, both Medicare and non-Medicare. This coverage does not apply if the patient was pronounced dead prior to arrival at the hospital.

20.3 - *Encounter Defined*

(Rev. 82; Issued: 02-08-08; Effective: 01-01-08; Implementation: 03-10-08)
Source: 42 CFR 410.2

A hospital outpatient “encounter” is a direct personal contact between a patient and a physician, or other person who is authorized by State licensure law and, if applicable, by hospital or CAH staff bylaws, to order or furnish hospital services for diagnosis or treatment of the patient.

20.4 - *Outpatient Diagnostic Services*

(Rev. 82; Issued: 02-08-08; Effective: 01-01-08; Implementation: 03-10-08)

20.4.1 - *Diagnostic Services Defined*

(Rev. 82; Issued: 02-08-08; Effective: 01-01-08; Implementation: 03-10-08)

A service is “diagnostic” if it is an examination or procedure to which the patient is subjected, or which is performed on materials derived from a hospital outpatient, to obtain information to aid in the assessment of a medical condition or the identification of a disease. Among these examinations and tests are diagnostic laboratory services such as hematology and chemistry, diagnostic x-rays, isotope studies, EKGs, pulmonary function studies, thyroid function tests, psychological tests, and other tests given to determine the nature and severity of an ailment or injury.

20.4.4 - Coverage of Outpatient Diagnostic Services

(Rev. 82; Issued: 02-08-08; Effective: 01-01-08; Implementation: 03-10-08)

Source: 42 CFR 410.28

Covered diagnostic services to outpatients include the services of nurses, psychologists, technicians, drugs and biologicals necessary for diagnostic study, and the use of supplies and equipment. When a hospital sends hospital personnel and hospital equipment to a patient’s home to furnish a diagnostic service, Medicare covers the service as if the patient had received the service in the hospital outpatient department.

For services furnished before August 1, 2000, hospital personnel may provide diagnostic services outside the hospital premises without the direct personal supervision of a physician. For example, if a hospital laboratory technician is sent by the hospital to a patient’s home to obtain a blood sample for testing in the hospital’s laboratory, the technician’s services are a covered hospital service even though a physician was not with the technician.

For services furnished on or after August 1, 2000, Medicare Part B makes payment for hospital or CAH diagnostic services furnished to outpatients, including drugs and biologicals required in the performance of the services (even if those drugs or biologicals are self-administered), if those services meet the following conditions:

- 1. They are furnished by the hospital or under arrangements made by the hospital or CAH with another entity (see §20.1 of this chapter).*
- 2. They are ordinarily furnished by, or under arrangements made by, the hospital or CAH to its outpatients for the purpose of diagnostic study.*
- 3. They would be covered as inpatient hospital services if furnished to an inpatient.*
- 4. Payment is allowed under the hospital outpatient prospective payment system for diagnostic services furnished at a facility that is designated as provider-based only when those services are furnished under the appropriate level of supervision specified in accordance with the definitions in 42 CFR 410.32(b)(3)(i), (b)(3)(ii), and (b)(3)(iii), and as described in chapter 15 of this manual, Section 80 “Requirements for Diagnostic X-ray, Diagnostic Laboratory, and Other Diagnostic Tests,” as though they are being furnished in a physician office or clinic setting.*

For services furnished on or after February 21, 2002, the provisions of paragraphs (a) and (d)(2) through (d)(4), inclusive, of 42 CFR 410.32 apply to all diagnostic laboratory tests furnished by hospitals and CAHs to outpatients.

20.4.5 - Outpatient Diagnostic Services Under Arrangements
(Rev. 82; Issued: 02-08-08; Effective: 01-01-08; Implementation: 03-10-08)

When the hospital makes arrangements with others for diagnostic services, such services are covered under Part B as diagnostic tests whether furnished in the hospital or in other facilities.

Independent laboratory services furnished to an outpatient under arrangements with the hospital are covered only under the "diagnostic laboratory tests" provisions of Part B (see section 10, above), but are to be billed along with other services to outpatients. See the Medicare Benefit Policy Manual, Pub. 100-02, Chapter 1, "Inpatient Hospital Services," section 50.3, for: (1) the definition of an independent clinical laboratory; (2) the requirements which such a laboratory must meet; and (3) instructions to the intermediary when it is not approved. The "cost" to the hospital for diagnostic laboratory services for outpatients obtained under arrangements is the reasonable charge by the laboratory.

Laboratory services may also be furnished to a hospital outpatient under arrangements by:

- 1. The laboratory of another participating hospital; or*
- 2. The laboratory of an emergency hospital or participating skilled nursing facility that meets the hospital conditions of participation relating to laboratory services.*

20.5 - Outpatient Therapeutic Services
(Rev. 82; Issued: 02-08-08; Effective: 01-01-08; Implementation: 03-10-08) Sources: 42 CFR 410.27; 65 FR 18536, April 7, 2000

20.5.1- Coverage of Outpatient Therapeutic Services Incident to a Physician's Service Furnished on or After August 1, 2000
(Rev. 82; Issued: 02-08-08; Effective: 01-01-08; Implementation: 03-10-08)

Therapeutic services and supplies which hospitals provide on an outpatient basis are those services and supplies (including the use of hospital facilities) which are incident to the services of physicians in the treatment of patients. Such services include clinic services and emergency room services. Policies for hospital services incident to physicians' services rendered to outpatients differ in some respects from policies that pertain to "incident to" services furnished in office and physician-directed clinic settings. See the Medicare Policy Manual, Pub 100-02, Chapter 15, "Covered Medical and Other Health Services", section 60.

To be covered as incident to physicians' services, the services and supplies must be furnished *by the hospital or CAH or under arrangement made by the hospital or CAH (see section 20.1.1 of this chapter)*. The services and supplies must be furnished as an integral, although incidental, part of the physician's professional service in the course of treatment of an illness or injury.

The services and supplies must be furnished in the hospital or at a department of the hospital which has provider-based status in relation to the hospital under 42 CFR §413.65 of the Code of Federal Regulations. The services and supplies must be furnished on a physician's order *(or on the order of nonphysician practitioners working within their scope of work and the state and local policies)* by hospital personnel and under a physician's supervision, *as described below*. This does not mean that each occasion of service by a nonphysician need also be the occasion of the actual rendition of a personal professional service by the physician *responsible for care of the patient*. However, during any course of treatment rendered by auxiliary personnel, the physician must personally see the patient periodically and sufficiently often to assess the course of treatment and the patient's progress and, where necessary, to change the treatment regimen. A hospital service or supply would not be considered incident to a physician's service if the attending physician merely wrote an order for the services or supplies and referred the patient to the hospital without being involved in the management of that course of treatment.

The physician supervision requirement is generally assumed to be met where the services are performed on hospital premises. The hospital medical staff that supervises the services need not be in the same department as the ordering physician. However, if the services are furnished *at a department of the hospital which has provider-based status in relation to the hospital under 42 CFR 413.65 of the Code of Federal Regulations, the services* must be rendered under the direct supervision of a physician who is treating the patient. *"Direct supervision" means the physician must be present and on the premises of the location and immediately available to furnish assistance and direction throughout the performance of the procedure. It does not mean that the physician must be present in the room when the procedure is performed.*

If a hospital therapist, other than a physical, occupational or speech -language pathologist, goes to a patient's home to give treatment unaccompanied by a physician, the therapist's services would not be covered. See the Medicare Benefit Policy Manual, Pub. 100-02, Chapter 15, "Covered Medical and Other Health Services," sections 220 and 230 for outpatient physical therapy and speech-language pathology coverage conditions.

20.6 - Outpatient Observation Services (Rev. 82; Issued: 02-08-08; Effective: 01-01-08; Implementation: 03-10-08)

A. Outpatient Observation Services Defined

Observation care is a well-defined set of specific, clinically appropriate services, which include ongoing short term treatment, assessment, and reassessment before a decision can be made regarding whether patients will require further treatment as hospital inpatients or if they are able to be discharged from the hospital. Observation status is commonly assigned to patients who present to the emergency department and who then require a significant period of treatment or monitoring in order to make a decision concerning their admission or discharge.

Observation services are covered only when provided by the order of a physician or another individual authorized by State licensure law and hospital staff bylaws to admit patients to the hospital or to order outpatient tests. In the majority of cases, the decision whether to discharge a patient from the hospital following resolution of the reason for the observation care or to admit the patient as an inpatient can be made in less than 48 hours, usually in less than 24 hours. In only rare and exceptional cases do reasonable and necessary outpatient observation services span more than 48 hours.

Hospitals may bill for patients who are *directly admitted to the hospital for outpatient observation services*. A “direct admission” occurs when a physician in the community refers a patient to the hospital for observation, bypassing the clinic or emergency department (ED). Effective for services furnished on or after January 1, 2003, hospitals may bill for patients directly admitted for observation services.

See, the Medicare Claims Processing Manual, Pub. 100-04, chapter 4, section 290, at <http://www.cms.hhs.gov/manuals/downloads/clm104c04.pdf> for billing and payment instructions for outpatient observation services.

B. Coverage of Outpatient Observation Services

When a physician orders that a patient be placed under observation care, the patient’s status is that of an outpatient. The purpose of observation is to determine the need for further treatment or for inpatient admission. Thus, a patient *receiving observation services* may improve and be released, or be admitted as an inpatient (see Pub. 100-02, Medicare Benefit Policy Manual, Chapter 1, Section 10 “Covered Inpatient Hospital Services Covered Under Part A” at <http://www.cms.hhs.gov/manuals/Downloads/bp102c01.pdf>). *For more information on correct reporting of observation services, see the Medicare Claims Processing Manual, Pub. 100-04, chapter 4, section 290.2.2.)*

All hospital observation services, regardless of the duration of the observation care, that are medically reasonable and necessary are covered by Medicare. Observation services are reported using HCPCS code G0378 (Hospital observation service, per hour). Beginning January 1, 2008, HCPCS code G0378 for hourly observation services is assigned status indicator N, signifying that its payment is always packaged. No separate payment is made for observation services reported with HCPCS code G0378. In most circumstances, observation services are supportive and ancillary to the other separately payable services provided to a patient. In certain circumstances when observation care

is billed in conjunction with a high level clinic visit (Level 5), high level emergency department visit (Level 4 or 5), critical care services, or direct admission to observation as an integral part of a patient's extended encounter of care, payment may be made for the entire extended care encounter through one of two composite APCs when certain criteria are met. For information about billing and payment methodology for observation services in years prior to CY 2008, see the Medicare Claims Processing Manual, Pub. 100-04, chapter 4, sections 290.3-290.4. For information about payment for extended assessment and management under composite APCs, see section 290.5.

Payment for all reasonable and necessary observation services is packaged into the payments for other separately payable services provided to the patient in the same encounter. Observation services that are packaged through assignment of status indicator N are covered OPPS services. Since the payment for these services is included in the APC payment for other separately payable services on the claim, hospitals must not bill Medicare beneficiaries directly for the packaged services.

C. Services Not Covered by Medicare and Notification to the Beneficiary

In making the determination whether an ABN can be used to shift liability to a beneficiary for the cost of non-covered items or services related to an encounter that includes observation care, the provider should follow a two step process. First, the provider must decide whether the item or service meets either the definition of observation care or would be otherwise covered. If the item or service does not meet the definitional requirements of any Medicare-covered benefit under Part B, then the item or service is not covered by Medicare and an ABN is not required to shift the liability to the beneficiary. However, the provider may choose to provide voluntary notification for these items or services.

Second, if the item or service meets the definition of observation services or would be otherwise covered, then the provider must decide whether the item or service is "reasonable and necessary" for the beneficiary on the occasion in question, or if the item or service exceeds any frequency limitation for the particular benefit or falls outside of a timeframe for receipt of a particular benefit. In these cases, the ABN would be used to shift the liability to the beneficiary (see the Medicare Claims Processing Manual; Pub. 100-04, Chapter 30, "Financial Liability Protections," Section 20, at <http://www.cms.hhs.gov/manuals/downloads/clm104c30.pdf> for information regarding Limitation On Liability (LOL) Under §1879 Where Medicare Claims Are Disallowed).

If an ABN is not issued to the beneficiary, the provider may be held liable for the cost of the item or service unless the provider/supplier is able to demonstrate that they did not know and could not have reasonably been expected to know that Medicare would not pay for the item or service.

70.5 - Laboratory Services Furnished to Nonhospital Patients by Hospital Laboratory

(Rev. 82; Issued: 02-08-08; Effective: 01-01-08; Implementation: 03-10-08)

A nonhospital patient is an individual who is neither an inpatient nor outpatient of the hospital furnishing the service. (See the Medicare Benefit Policy Manual, Pub. 100-02, Chapter 1, "Inpatient Hospital Services," section 10, for the definition of a hospital inpatient and section 20.1 for the definition of a hospital outpatient). Nonhospital patients primarily are individuals from whom a specimen had been taken and sent to the hospital for analysis *and the patient does not receive hospital outpatient services on the same day. For all hospitals except CAHs and Maryland waiver hospitals, if a beneficiary receives hospital outpatient services on the same day as a specimen collection and laboratory test, then the patient is considered to be a registered hospital outpatient and cannot be considered to be a non-patient on that day for purposes of the specimen collection and laboratory test. However if the non-CAH or Maryland waiver hospital only collects or draws a specimen from the beneficiary and the beneficiary does not also receive hospital outpatient services on that day, the hospital may choose to register the beneficiary as an outpatient for the specimen collection or bill for these services as non-patient on the 14X bill type.*

For CAHs, payment for clinical diagnostic laboratory tests is made at 101 percent of reasonable cost, only if the individuals are outpatients of the CAH, as defined in 42 CFR 410.2, and are physically present in the CAH at the time the specimens are collected. Clinical diagnostic laboratory tests performed for persons who are not physically present (non-patients) at the CAH when the specimens are collected are made in accordance with the provisions of sections 1833(a)(1)(D) and 1833(a)(2)(D) of the Social Security Act. See also 42 CFR 413.70(b)(iii). Similarly, for Maryland waiver hospitals, the waiver is limited to services to inpatients and registered outpatients as defined in 42 CFR 410.2. Therefore payment for non-patients (specimen only, TOB 14X) who are not registered outpatients at the time of specimen collection will be made on the clinical diagnostic laboratory fee schedule. Such services are covered to the extent appropriate.

See the Medicare Claims Processing Manual, *Pub. 100-04*, Chapter 16, "Laboratory Services from Independent Labs, Physicians, and Providers," section 40.3, for billing and payment of clinical diagnostic laboratory services for patients and non-patients.

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

Section B: *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.