Medicare Claims Processing Manual

Chapter 16 - Laboratory Services

May 12, 2003

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10 - Background

(Rev.)

B3-2070, B3-2070.1, B3-4110.3, B3-5114

Diagnostic x-ray, laboratory, and other diagnostic tests, including materials and the services of technicians, are covered under the Medicare Program. Some clinical laboratory procedures or tests require Food and Drug Administration (FDA) approval before coverage is provided.

Regardless of whether a diagnostic laboratory test is performed in a physician's office, by an independent laboratory, by a hospital laboratory for its outpatients or nonpatients, in a rural health clinic or in an HMO or Health Care Prepayment Plan (HCPP) for a patient who is not a member, it is considered a laboratory service for billing. When a hospital laboratory performs laboratory tests for nonhospital patients, the laboratory is functioning as an independent laboratory, and still bills the intermediary. Also, when physicians and laboratories perform the same test, whether manually or with automated equipment, the services are deemed similar.

Laboratory services furnished by an independent laboratory are covered under medical insurance if the laboratory is an approved Independent Clinical Laboratory. However, as is the case of all diagnostic services, in order to be covered these services must be related to a patient's illness or injury (or symptom or complaint) and ordered by a physician. A small number of laboratory tests can be covered as a preventive screening service.

See the Medicare Benefit Policy Manual, Chapter 15, §80, for detailed coverage requirements.

See the Medicare Program Integrity Manual, Chapter 10, for laboratory/supplier enrollment guidelines.

See the Medicare State Operations Manual for laboratory/supplier certification requirements.

10.1 - Definitions

(Rev.)

B3-2070.1, B3-2070.1.B, RHC-406.4

"Independent Laboratory" - An independent laboratory is one which is independent both of an attending or consulting physician's office and of a hospital which meets at least the requirements to qualify as an emergency hospital as defined in §1861(e) of the Social Security Act (the Act.) (See the Medicare Benefits Policy Manual, Chapter 15, §80.1.1, for detailed discussion.)

A laboratory which is operated by or under the supervision of a hospital (or the organized medical staff of the hospital) which does not meet at least the definition of an emergency hospital is considered to be an independent laboratory. However, a laboratory serving hospital patients and operated on the premises of a hospital which meets the definition of an emergency hospital is presumed to be subject to the supervision of the hospital or its organized medical staff and is not an independent laboratory. A laboratory which a physician or group of physicians maintains for performing diagnostic tests in connection with his own or the group practice is also not considered to be an independent laboratory.

"Clinical Laboratory" - A clinical laboratory is a laboratory where microbiological, serological, chemical, hematological, radiobioassay, cytological, immuno-hematological, or pathological examinations are performed on materials derived from the human body, to provide information for the diagnosis, prevention, or treatment of a disease or assessment of a medical condition. (See also the Medicare Benefits Policy Manual, Chapter 15, §80.1.2)

"Qualified Hospital" - A qualified hospital laboratory is one which provides some clinical laboratory tests 24 hours a day, 7 days a week, in order to serve a hospital's emergency room which is available to provide services 24 hours a day, 7 days a week. To meet this requirement, a hospital must have physicians physically present or available within 30 minutes through a medical staff call roster to handle emergencies 24 hours a day, 7 days a week. Hospital laboratory technologists must be on duty or on call at all times to provide testing for the emergency room.

"Hospital Outpatient" - A hospital outpatient is a person who has not been admitted as an inpatient but is registered on the hospital's records as an outpatient and receives services (rather than supplies alone) from the hospital. Where a tissue sample, blood sample, or specimen is taken by personnel who are not employed by the hospital, and is sent to the hospital for tests, the tests are "nonpatient" hospital services since the patient does not directly receive services from the hospital. 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 an outpatient.

10.2 - General Explanation of Payment

(Rev.)

B3-5114, HO-437, A3-3628, B3-5114.1

Outpatient laboratory services can be paid in different ways:

- Physician Fee Schedule;
- Reasonable costs (Critical Access Hospitals (CAH) only);

  NOTE: When the CAH bills a 14X bill type as a reference laboratory, they are paid under the laboratory fee schedule and not reasonable cost.

- Laboratory Fee Schedule;
- Outpatient Prospective Payment System, (OPPS) except the state of Maryland that is a waiver state; or
- Reasonable Charge

Annually, CMS distributes a list of codes and indicates the payment method. Carriers and Intermediaries pay as directed by this list. Neither deductible nor coinsurance apply to HCPCS codes paid under the laboratory fee schedule, including reasonable cost payments made to CAHs. The majority of outpatient laboratory services are paid under the laboratory fee schedule or OPPS.

Carriers and intermediaries are responsible for applying the correct fee schedule for payment of clinical laboratory tests. Intermediaries must determine which hospitals meet the criteria for payment at the 62 percent fee schedule. Only sole community hospitals with qualified hospital laboratories are eligible for payment under the 62 percent fee schedule. Generally, payment for diagnostic laboratory tests that are not subject to the clinical laboratory fee schedule is made in accordance with the reasonable charge or physician fee schedule methodologies (or reasonable costs for CAHs).

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

(Rev.)

HO-437,A3-3628, PM AB-98-7, B3-5114.1

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.

The CMS furnishes the proper amount to pay for each HCPCS code for each local geographic area to carriers and intermediaries annually. 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.)

HO-437, A3-3628, B3-5114.1.C

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

The fee schedule amounts are updated annually to reflect changes in the Consumer Price Index (CPI) for all Urban Consumers (U.S. city average), or as otherwise specified by legislation. Individual carriers performed the updates from 1985 through 1993. In 1994, CMS took over the annual update and distribution of clinical laboratory fee schedules.

Effective for hospital outpatient tests furnished by a hospital on or after April 1, 1988, to receive the 62 percent fee the hospital must also be a sole community hospital. In all other cases 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 intermediary or the RO.

For tests to hospital nonpatients, the fee is set at 60 percent. Where a hospital laboratory acts as an independent laboratory, i.e., performs tests for persons who are nonhospital patients or, where, commencing January 1, 1987, 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.

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. Where a tissue sample, blood sample, or specimen is taken by personnel who are not employed 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. 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 classified as an outpatient.

20.2 - Annual Fee Schedule Updates

(Rev.)

The fee schedule amounts are adjusted annually to reflect changes in the Consumer Price Index (CPI) for all Urban Consumers (U.S. city average), or as otherwise specified by legislation. Coding and pricing changes are also determined by CMS and published for contractor use and also on the CMS Web site. A CMS issued Program Memorandum informs contractors when and where the updates are published.

30 - Special Payment Considerations

(Rev.)

30.1 - Mandatory Assignment for Laboratory Tests

(Rev.)

B3-5114.1

Unless a laboratory, physician, or medical group accepts assignment, no Part B payment may be made for laboratory tests. Laboratories, physicians, or medical groups that have entered into a participation agreement must accept assignment. Effective January 1, 1988, sanctions of double the violation charges, civil money penalties (up to $2000 per violation), and/or exclusion from the program for a period of up to five years may be imposed on physicians and laboratories, with the exception of rural health clinic laboratories, that knowingly, willfully, and repeatedly bill patients on an unassigned basis. However, sole community physicians and physicians who are the sole source of an essential specialty in a community are not excluded from the program. Whenever a contractor is notified of a sanction action for this reason, the carrier does not pay for any laboratory services unless the services were furnished within 15 days after the date on the exclusion or suspension notice to the practitioner, and:

- It is the first claim filed for services rendered to that beneficiary after the date on the notice of suspension or exclusion; or

- It is filed with respect to services furnished within 15 days of the date on the first notice of denial of claims to the beneficiary. (Fifteen days are allowed for the notice to reach the beneficiary.)

Refer any questions on payment procedures to the Sanctions Coordinator in the RO.

Laboratory claims, which are inadvertently submitted as unassigned are processed as if they were assigned. (See §50.)

For purposes of this section, the term assignment includes assignment in the strict sense of the term as well as the procedure under which payment is made, after the death of the beneficiary, to the person or entity which furnished the service, on the basis of that person's or entity's agreement to accept the Medicare payment as the full charge or fee for the service.

30.1.1 - Rural Health Clinics

(Rev.)

PM A-99-8, Rev. 810, CR 1133 PM A-00-30

Rural Health Clinics (RHCs) must furnish the following laboratory services to be approved as an RHC. However, these and other laboratory services that may be furnished are not included in the encounter rate and must be billed separately:

- Chemical examinations of urine by stick or tablet method or both;
- Hemoglobin or hematocrit;
- Blood sugar;
- Examination of stool specimens for occult blood;
- Pregnancy tests; and
- Primary culturing for transmittal to a certified laboratory (No CPT code available).

Effective January 1, 2001, freestanding RHCs/FQHCs bill all laboratory services to the carrier, and provider based RHCs/FQHCS bill all laboratory tests to the intermediary under the host provider's bill type. In either case payment is made under the fee schedule. HCPCS codes are required for laboratory services. (See §40.4 for details on RHC billing.)

30.2 - Deductible and Coinsurance Application for Laboratory Tests

(Rev.)

B3-2462, B3-5114.1, A3-3215, HHA-160

Neither the annual cash deductible nor the 20 percent coinsurance apply to:

- Clinical laboratory tests performed by a physician, laboratory, or other entity paid on an assigned basis;
- Specimen collection fees; or
- Travel allowance.

Codes on the physician fee schedule are generally subject to the Part B deductible and coinsurance, although exceptions may be noted for a given code in the MPFS or through formal Medicare instructions such as program memoranda and requirements for specific services noted in this manual.

Any laboratory code paid at reasonable charge is subject to the Part B deductible and coinsurance, unless otherwise specified in the description of coverage and payment rules.

Neither deductible nor coinsurance are applied to payment for codes on the laboratory fee schedule that are made to Critical Access Hospital.

30.3 - Method of Payment for Clinical Laboratory Tests - Place of Service Variation

(Rev.)

HO-437, A3-3628, B3-5114.1, PM A-01-31

The following apply in determining the amount of Part B payment for clinical laboratory tests, including those furnished under method II for ESRD beneficiaries:

Independent laboratory or a physician or medical group - Payment to an independent laboratory or a physician or medical group is the lesser of the actual charge, the fee schedule amount or the national limitation amount, and the Part B deductible and coinsurance do not apply.

Reference laboratory - For tests performed by a reference laboratory, the payment is the lesser of the actual charge by the billing laboratory, the fee schedule amount, or the national limitation amount. (See §50.5 for carrier jurisdiction details.) Part B deductible and coinsurance do not apply.

Outpatient or a nonpatient of the hospital - Payment to a hospital for tests furnished for an outpatient or a nonpatient of the hospital is the lesser of the actual charge, the 60

percent fee schedule amount, or the 60 percent NLA. Part B deductible and coinsurance do not apply.

Inpatient without Part A - Payment to a hospital for tests performed for an inpatient without Part A coverage is made on a reasonable cost basis and is subject to Part B deductible and coinsurance. Payment to a SNF inpatient without Part A coverage is made under the laboratory fee schedule.

Inpatient or SNF patient with Part A - Payment to a hospital or SNF for laboratory tests furnished to an inpatient whose stay is covered under Part A, is included in the PPS rate for PPS facilities or is made on a reasonable cost basis for non-PPS hospitals/SNFs.

Sole community hospital - Payment to a sole community hospital for tests furnished for an outpatient of that hospital, is the least of the actual charge, the 62 percent fee schedule amount, or the 62 percent NLA. The Part B deductible and coinsurance do not apply.

Waived Hospitals - Payment to a hospital which has been granted a waiver of Medicare payment principles for outpatient services is subject to Part B deductible and coinsurance unless otherwise waived as part of an approved waiver. Specifically, laboratory fee schedules do not apply to laboratory tests furnished by hospitals in States or areas which have been granted demonstration waivers of Medicare reimbursement principles for outpatient services. The State of Maryland has been granted such demonstration waivers. This also may apply to hospitals in States granted approval for alternative payment methods for paying for hospital outpatient services under §1886(c) of the Act.

Critical Access Hospital - Payment to a Medicare Critical Access Hospital (CAH) for clinical laboratory services furnished as an outpatient service is made on a reasonable cost basis. Critical Access Hospitals are paid under the fee schedule for services when they function as a reference laboratory (bill type 14X). Beneficiaries are not liable for any coinsurance, deductible, co-payment, or other cost sharing amount with respect to CAH clinical laboratory services.

Dialysis facility - Payment to a hospital-based or independent dialysis facility for laboratory tests included under the ESRD composite rate payment and performed for a patient of that facility, is included in the facility's composite rate payment for these tests and is subject to the Part B deductible and coinsurance. Laboratory tests that are not included under the ESRD composite rate payment and are performed by an independent laboratory or a provider-based laboratory for dialysis patients of independent dialysis facilities or provider based facilities, are paid in addition to the composite rate payment and are subject to the fee schedule limits. This also applies to all laboratory tests furnished to home dialysis patients who have selected Payment Method II. These limits are 60 percent for all tests unless performed by a qualified hospital laboratory in a sole community hospital. In this case the 62 percent rate applies. The laboratory performing the tests must bill.

Rural health clinic - Payment to a rural health clinic (RHC) for laboratory tests performed for a patient of that clinic is not included in the all-inclusive rate and may be

billed separately by the laboratory (including a laboratory that is part of a hospital that hosts a hospital based RHC). Payment for the laboratory service is not subject to Part B deductible and coinsurance. (See §40.4 for details on RHC billing.)

Enrolled in Managed Care - Payment to a participating health maintenance organization (HMO) or health care prepayment plan (HCPP) for laboratory tests provided to a Medicare beneficiary who is an enrolled member is included in the monthly capitation amount.

Nonenrolled Managed Care - Payment to a participating HMO or HCPP for laboratory tests performed for a patient who is not a member is the lesser of the actual charge, or the fee schedule national limitation amount. The Part B deductible and coinsurance do not apply.

Hospice - Payment to a hospice for laboratory tests performed by the hospice is included in the hospice rate.

30.4 - Payment for Review of Laboratory Test Results by Physician

(Rev.)

B3-5114.2

Reviewing results of laboratory tests, phoning results to patients, filing such results, etc., are services which are covered by the program, and payment for these services is included in the physician fee schedule payment for the evaluation and management (E and M) services to the patient. Visit services entail a wide range of components and activities that may vary somewhat from patient to patient. The CPT lists different levels of E and M services for both new and established patients and describes services which are included as part of E and M services. Such activities include obtaining, reviewing, and analyzing appropriate diagnostic tests.

40 - Billing for Clinical Laboratory Tests

(Rev.)

40.1 - Laboratories Billing for Referred Tests

(Rev.)

B3-5114.1.E, Title XVIII §1833(h)(5)(A) of the Act

The rules for billing for referred tests is a carrier only instruction. In accordance with §6111(b) of OBRA of 1989 as amended by §4154 of OBRA of 1990, a referring laboratory may bill for tests for Medicare beneficiaries performed on or after May 1, 1990, by a reference laboratory only if it meets certain exceptions. In the case of a test performed at the request of a laboratory by another laboratory, payment may be made to the referring laboratory but only if:

- The referring laboratory is located in, or is part of, a rural hospital;

- The referring laboratory is wholly owned by the entity performing such test, the referring laboratory wholly owns the entity performing such test, or both the referring laboratory and the entity performing such test are wholly-owned by a third entity (collectively, a related referring laboratory); or

- Not more than 30 percent of the clinical laboratory tests for which a nonrelated referring laboratory receives requests for testing during the year in which the test is performed are performed by another laboratory.

In the case of a clinical laboratory test provided under an arrangement (as defined in §1861(w)(1)) made by a hospital, critical access hospital or skilled nursing facility, payment is made to the hospital or skilled nursing facility.

Examples of 30 Percent Exception

1. A laboratory receives requests for 200 tests, performs 139 tests, and refers 61 tests to a nonrelated laboratory.

   All referred tests are counted. Thus, 30.5 percent (61/200) of the tests are considered referred tests and, since this exceeds the 30 percent standard, the laboratory may not bill for any referred tests for Medicare beneficiaries.

2. A laboratory receives requests for 200 tests, performs 139 tests and refers 15 to a related laboratory and 46 to a nonrelated laboratory. Only 23 percent of the tests were referred to nonrelated laboratories, which is less than 30 percent. The laboratory may bill for all tests.

NOTE: This provision of §6111(b) of OBRA of 1989 has no effect on hospitals that are paid under §1833(h)(5)(A)(iii).

40.2 - Payment Limit for Purchased Services

(Rev.)

MCM-15048

If a physician or laboratory bills for a laboratory test performed by an outside supplier, the fee schedule amount for the purchased service equals the lower of the billing physician's/laboratory's fee schedule or the price paid for the service.

For purchased services, the billing physician must identify the supplier (including the supplier's provider number) and the amount the supplier charged net of any discounts on the claim.

40.3 - Hospital Billing Under Part B

(Rev.)

HO-437, A3-3628

Hospital laboratories, billing for either outpatient or nonpatient claims, bill the intermediary. Neither deductible nor coinsurance applies to laboratory tests paid under the fee schedule. Hospitals must follow requirements for submission of the CMS-l450 (see the Medicare Claims Processing Manual, Chapter 25, "Completing and Processing UB-92 Data Set," for billing requirements).

When the hospital obtains laboratory tests for outpatients under arrangements with clinical laboratories or other hospital laboratories, only the hospital can bill for the arranged services.

If all tests are for a nonpatient, the hospital may submit one bill and be reimbursed at 60 percent.

If the hospital is a sole community hospital identified in the PPS Provider Specific File with a qualified hospital laboratory identified on the hospital's certification, tests for outpatients are reimbursable at 62 percent. If tests are for an outpatient, those referred to a reference laboratory are considered nonpatient tests reimbursable at 60 percent.

If the hospital bills for both, it should prepare two bills: one for its own laboratory tests reimbursable at 62 percent, the other for the tests referred to the reference laboratory reimbursable at 60 percent. The hospital must include in the bill for tests performed by the reference laboratory nonpatient type of bill coding e.g.,14X).

It should also include billing for fee schedule laboratory tests with billing for other outpatient services to the same beneficiary on a single bill except where billing for a reference laboratory as described above. Hospitals should not submit separate bills for laboratory tests performed in different departments on the same day.

(See §50.4 for related claims processing instructions)

40.3.1 - Critical Access Hospital (CAH) Outpatient Laboratory Service

(Rev.)

HO-437, A3-3628, PM A01-31

Effective for services furnished on or after the enactment of Balanced Budget Refinement Act of 1999 (BBRA), Medicare beneficiaries are not liable for any coinsurance, deductible, co-payment, or other cost sharing amount with respect to clinical laboratory services furnished as a Critical Access Hospital (CAH) outpatient service. This change is effective for claims with dates of service on or after November 29, 1999 that were received July 1, 2001 or later.

For CAH bill type 85x, the laboratory fees are paid at cost with no cost-sharing.

When the CAH bills a 14X bill type as a reference laboratory, it is paid the laboratory fee schedule and not at reasonable cost.

40.4 - Special Skilled Nursing Facility (SNF) Billing Exceptions for Laboratory Tests

(Rev.)

SNF 541, A3-3137.1, HO-437, B3-5114.1

When an SNF furnishes laboratory services directly, it must have a Clinical Laboratory Improvement Act (CLIA) number or a CLIA certificate of waiver. Normally payment under Part B for clinical laboratory tests can be made only to the entity that performed the test. However, the law permits SNFs to furnish laboratory services under an arrangement and to bill for those tests, regardless of whether the SNF itself can furnish the service. Section 1833(h)(5) of the Act (as enacted by The Deficit Reduction Act of 1984, P.L. 98-369) requires the establishment of a fee schedule for clinical laboratory tests paid under Part B and also requires that, with certain exceptions, only the entity that performed the test may be paid.

The fee schedule applies to all SNF clinical laboratory services. Charges for services paid under any fee schedule must be recorded by the SNF as non-Medicare charges for the purpose of apportioning the SNF's department costs for the cost report.

Where a SNF operates a laboratory that provides laboratory services to patients other than its own patients, it is functioning as a clinical laboratory. The billing for these laboratory services depends upon the HCPCS code as defined in the CMS annual fee schedule releases (laboratory and MPFS), and the arrangements made for payment with the referring entity (e.g., does the SNF or the referring entity bill under the agreement between the two). The SNF is responsible for ascertaining the necessary information for billing the intermediary. Any questions must be referred to the intermediary.

40.4.1 - Which Contractor to Bill for Laboratory Services Furnished to a Medicare Beneficiary in a Skilled Nursing Facility (SNF)

(Rev.)

Inpatient Part A beneficiary - SNF bills the intermediary. The service is considered included in SNF PPS payment.

Inpatient Part B beneficiary (benefits exhausted or no Part A entitlement) - SNFs may provide service and bill, may obtain service under arrangement and bill, or may have agreement with reference laboratory for the reference laboratory to provide the service and have the reference laboratory bill. Regardless of who bills, the service is paid under

fee schedule. This applies regardless of whether the beneficiary is in a Medicare certified bed or not.

Outpatient Part B - Same as inpatient Part B.

40.5 - Rural Health Clinic (RHC) Billing

(Rev.)

B3-3628

For independent RHCs, laboratory services provided in the RHC's laboratory are not included in the all-inclusive rate payment to the RHC and may be billed separately to the carrier. This includes the six basic laboratory tests required for certification as well as any other laboratory tests provided in the RHC laboratory. (Note: If the RHC sends laboratory services to an outside laboratory, the outside laboratory bills the Part B carrier for the tests). If the RHC laboratory becomes certified as a clinical laboratory, all laboratory tests performed in the laboratory will be billed to the laboratory's Part B carrier. Laboratory tests are not included as RHC costs nor as part of the RHC all-inclusive rate payment.

For provider based RHCs the rules in the preceding paragraph apply except billing for tests provided in the provider's laboratory are billed by the provider to the intermediary.

40.6 - Billing for End Stage Renal Disease (ESRD) Related Laboratory Tests

(Rev.)

PM AB-98-7, PRM1 2711, B3-4270.2, PM A-03-033

Hemodialysis, Intermittent Peritoneal Dialysis (IPD), and Continuous Cycling Peritoneal Dialysis (CCPD) Tests

Laboratory tests for hemodialysis, intermittent peritoneal dialysis (IPD), and continuous cycling peritoneal dialysis (CCPD) are normally included in the ESRD composite rate, with some exceptions. (See the Medicare Benefit Policy Manual Chapter 11, "End Stage Renal Disease (ESRD)," and the Medicare Claims Processing Manual, Chapter 8, "Outpatient ESRD (Hospital-Based and Independent RDF Facilities," for a description of what laboratory and other tests are included in the composite rate and when tests may be billed and paid in addition to the composite rate.)

Clinical laboratory tests included under the composite rate payment are paid through the composite rate paid by the intermediary. To determine if separate payment is allowed for noncomposite rate tests for a particular date of service, 50 percent or more of the covered tests must be noncomposite rate tests.

Medicare will apply the following to Automated Multi-Channel Chemistry (AMCC) tests for ESRD beneficiaries:

- Payment is at the lowest rate for services performed by the same provider, for the same beneficiary, for the same date of service.

- Identify for a particular date of service the AMCC tests ordered that are included in the composite rate and those that are not included. The composite rate tests are defined for Hemodialysis, Intermittent Peritoneal Dialysis (IPD), Continuous Cycling Peritoneal Dialysis (CCPD), and Hemofiltration (Attachment 1) and for Continuous Ambulatory Peritoneal Dialysis (CAPD) (Attachment 2).

- If 50 percent or more of the covered tests are included under the composite rate payment, then all submitted tests are included within the composite payment. In this case, no separate payment in addition to the composite rate is made for any of the separately billable tests.

- If less than 50 percent of the covered tests are composite rate tests, all AMCC tests submitted for that Date of Service (DOS) are separately payable.

- A noncomposite rate test is defined as any test separately payable outside of the composite rate or beyond the normal frequency covered under the composite rate that is reasonable and necessary.

(See §100.6 for details regarding pricing modifiers.)

The organ and disease oriented panels (80049, 80051, 80054, and 80058) are subject to the 50 percent rule. Laboratory tests that are not covered under the composite rate and that are furnished to CAPD end stage renal disease (ESRD) patients dialyzing at home are billed in the same way as any other test furnished home patients.

40.6.1 - Claims Processing for Separately Billable Tests for ESRD Beneficiaries

(Rev.)

ESRD clinical laboratory tests that are separately billable (medically necessary, but not covered under the ESRD composite rate) are paid to hospital-based facilities or independent laboratories in accordance with usual program rules for laboratory services. Claims for these laboratory tests must indicate why the laboratory services were required in the individual case. These payable ESRD laboratory tests include tests that are:

- Listed as reimbursed under the composite rate, but are furnished at a greater frequency than listed; or

- Not listed.

Clinical laboratory tests can be performed individually or in predetermined groups on automated profile equipment. If a test profile is performed see §40.6.1.1. If a clinical laboratory test is performed individually, see §40.6.1.2 or §40.6.1.3 depending upon whether the patient is treated in a hospital-based or independent dialysis facility

40.6.1.1 - Automated Profile Tests for ESRD Beneficiaries

(Rev.)

If clinical laboratory tests are performed as part of an automated profile, the following procedure applies:

- The intermediary/carrier determines which of the laboratory tests in the automated profile are covered under Medicare;

- All separately billable ESRD laboratory tests must be documented for medical necessity to the intermediary's/carrier's satisfaction; and

- The intermediary/carrier determines the allowable amount for the covered tests by comparing the total of (1) the allowable amounts for the individual covered tests performed with (2) the allowable amount for the panel; and selecting the lower of the two. If the payment allowance for the automated profile containing only the medically necessary tests is lower, the contractor must determine the percentage of covered tests included under the composite rate payment, then the entire automated profile is included in the composite rate. In this case, no separate payment in addition to the ESRD composite rate is made for any of the separately billable tests, and the entire cost of the automated profile must be allocated to the facility's routine laboratory cost center. If more than 50 percent of the covered tests are separately billable, the entire automated profile is considered separately billable. In this case, the entire automated profile is paid in addition to the ESRD composite rate, and the entire cost of the automated profile must be allocated to the nonroutine laboratory cost center for hospital-based facilities.

If the lower cost is the cost of the laboratory tests taken individually, the tests may be billed individually. In this case, the tests included under the composite rate are not billed or reimbursed separately, and the tests that are not included under the composite rate are billed and reimbursed separately. The costs are allocated to the routine and nonroutine cost centers, respectively.

40.6.1.2 - Separately Billable ESRD Laboratory Tests Furnished by Hospital-Based Facilities

(Rev.)

Hospital-based facilities are reimbursed for the separately billable ESRD laboratory tests furnished to their outpatients following the same rules that apply to all other Medicare covered outpatient laboratory services furnished by a hospital.

40.6.1.3 - Separately Billable ESRD Laboratory Tests Furnished to Patients of Independent Dialysis Facilities.

(Rev.)

All separately billable ESRD clinical laboratory services furnished to patients of independent dialysis facilities must be billed by and paid to the person or entity that performs the laboratory test in accordance with usual Medicare program rules. Independent dialysis facilities with appropriate clinical laboratory certification may bill their intermediary for any separately billable clinical laboratory tests they perform. Both laboratories and independent dialysis facilities are paid for separately billable clinical laboratory tests according to the Medicare clinical laboratory fee schedule.

40.7 - Billing for Noncovered Clinical Laboratory Tests

(Rev.)

B3-5114.1

Ordinarily, neither a physician nor a laboratory bills the Medicare Program for noncovered tests. However, if the beneficiary (or his/her representative) contends that a clinical laboratory test which a physician or laboratory believes is noncovered may be covered, the physician or laboratory must file a claim that includes the test to effectuate the beneficiary's right to a Medicare determination. The physician or laboratory annotates the claim that he/she believes that the test is noncovered and is submitting it at the beneficiary's insistence.

Before furnishing a beneficiary a test which the physician or laboratory believes is excluded from coverage as not reasonable and necessary (rather than excluded from coverage as part of a routine physical check-up), the physician or laboratory must obtain a signed Advanced Beneficiary Notice (ABN) from the beneficiary (or representative) that the physician or laboratory has informed him/her of the noncoverage of the test and that there will be a charge for the test. This protects the physician or laboratory against possible liability for the test under the limitation of liability provision.

Denials for laboratory services are subject to Advanced Beneficiary Notice requirements discussed in the Medicare Claims Processing Manual, Chapter 1, "General Billing Requirements," §60.

50 - Claims Processing

(Rev.)

50.1 - Referring Laboratories

(Rev.)

B3-5114.1

Effective with services rendered on or after January 1, 1991, carriers deny bills from a referring laboratory for tests performed by a reference laboratory unless the carrier is informed in writing by the referring laboratory that the referring laboratory meets one of the exception criteria in §40.1.

If it is later found that a referring laboratory does not, in fact, meet an exception criterion, the carrier should recoup payment for the referred tests improperly billed. When a laboratory, after carrier contacts, continually fails to follow instructions on identifying the laboratory actually performing a test when the performance of a test has been referred to another laboratory, the carrier will advise the RO. The RO will take whatever action is necessary to correct the problem.

50.2 - Physicians

(Rev.)

B3-4110.2

When a physician or medical group furnishes laboratory tests in an office setting and it is appropriate for them to be performed in the physician's office, no further development of the source of the laboratory tests is required.

If a claim or physician's bill raises a question as to the source of a laboratory test and it cannot be resolved from available information, carriers must request the source of the laboratory service from the physician.

When Part B payment for clinical laboratory tests is subject to the laboratory fee schedule, carriers must pay only the person or entity that performed or supervised the performance of the tests. However, carriers may also pay one physician for tests performed or supervised by another physician with whom he/she shares a practice, i.e., the two physicians are members of a medical group whose physicians bill in their own names rather than in the name of the group. Where the medical group bills in the name of the group for the services of the physician who performed or supervised the performance of these tests, carriers must pay the group if the claim is assigned.

50.2.1 - Assignment Required

(Rev.)

B3-4110.2

Carriers must:

- Pay for clinical laboratory services provided in the physician's office only on an assignment basis.

- Treat as assigned any claims for clinical laboratory services provided in the physician's office even if submitted on a non assigned basis or if the assignment option is not designated.

- Deny claims where it is apparent from the claims form or from other evidence that the beneficiary or provider refuses to assign. Use MSN notice 16.41 or 16.6 and remittance Remark code PR106 or CO111, as appropriate.

50.3 - Hospitals

(Rev.)

50.3.1 - Hospital-Leased Laboratories

(Rev.)

B3-4110.1

Carriers process claims from hospital laboratories that are leased by physicians and independent laboratories.

To process claims for services furnished by a hospital laboratory department operated on a lease or concession basis by a pathologist or by a nonphysician specialist such as a biochemist (with a visiting pathologist or outside independent laboratory doing the hospital's tissue work), carriers must ascertain if the laboratory has been approved by the RO.

Services furnished by a laboratory that does not meet the hospital laboratory conditions of participation and is operated under a lease arrangement in a domestic emergency hospital are covered only if they are emergency inpatient services payable under Part A.

Additional information concerning nonparticipating emergency hospital services is found in the Medicare Claims Processing Manual, Chapter 3, "Inpatient Part A Hospital," §110.

50.3.2 - Hospital Laboratory Services Furnished to Nonhospital Patients

(Rev.)

B3-4110.5, HO-460

When a hospital laboratory performs a laboratory service for a nonhospital patient, (i.e., for neither an inpatient nor an outpatient), the hospital bills its intermediary on the Form CMS-1450. If a carrier receives such claims, the carrier should deny them. When a hospital-leased laboratory performs a service for a nonhospital patient, it must bill the carrier.

50.4 - Reporting of Pricing Localities for Clinical Laboratory Services

(Rev.)

PM-B-97-12

For dates of services on or after January 1, 1998, CWF edits require that clinical laboratory services and drugs be reported with the appropriate carrierwide, statewide pricing locality. This edit ensures that valid pricing localities are submitted to CWF, and also promotes consistency in the reporting of pricing localities for clinical laboratory services and drugs.

Carriers must report pricing localities for clinical laboratory services and drugs to CWF using the following guidelines:

- Carriers assigned a single carrierwide, statewide pricing locality (i.e., a 00 or another single locality number) should submit that locality to CWF for clinical laboratory services and drugs.

- Carriers not assigned a single carrierwide, statewide pricing locality (i.e., more than one locality number) should use locality 00 for clinical laboratory services and drugs.

50.5 - Jurisdiction of Laboratory Claims

(Rev.)

B3-3102

Jurisdiction of payment requests for laboratory services furnished by an independent laboratory, except where indicated in §50.5.1 and §50.5.2, lies with the carrier serving the area in which the laboratory test is performed. Jurisdiction is not affected by whether or not the independent laboratory uses a central billing office and whether or not the laboratory provides services to customers outside its carrier's service area.

50.5.1 - Referral Laboratory Services

(Rev.)

B3-3102, B3-5114

The referring independent laboratory may bill for Medicare beneficiary tests if no more than 30 percent of the total annual clinical laboratory tests requested for the referring laboratory are performed by another laboratory.

If the specimen is drawn or received by an independent laboratory approved under the Medicare program and the laboratory performs a covered test but refers the specimen to another laboratory in a different carrier jurisdiction for additional tests, the carrier servicing the referring laboratory retains jurisdiction for services performed by the other laboratory only if it has, in house, the appropriate certification information as well as appropriate fee schedule allowance(s) of the performing laboratory. If the carrier with jurisdiction of the referring laboratory does not have this information, in house, the claims for services performed by other laboratories must be transferred to the carrier servicing the laboratory that performed the service. This rule applies whether or not the referring and reference laboratories are owned and controlled by the same entity or the reference laboratory deals only with other laboratories and not with patients and third party payers. In such cases, the referring independent laboratory must identify the performing laboratory on its bills.

NOTE: In no case should jurisdiction be determined by the location of a nonapproved pickup station.

If the approved independent laboratory which draws or receives the specimen performs no covered services, but refers the specimen to another independent laboratory in a different carrier jurisdiction, the rules cited above apply.

50.5.2 - Examples of Independent Laboratory Jurisdiction

(Rev.)

B3-3102

EXAMPLE 1

An independent laboratory located in Oregon performs laboratory services for physicians whose offices are located in several neighboring States. A physician from Nevada sends specimens to the Oregon laboratory.

If the laboratory sends the results to the physician and accepts assignment, the carrier in Oregon has jurisdiction.

EXAMPLE 2

American Laboratories, Inc., is an independent laboratory company with branch laboratories located in Philadelphia, PA and Wilmington, DE, as well as regional laboratories located in Millville, NJ and Boston, MA.

The Philadelphia laboratory receives a blood sample from a patient whose physician ordered a complete blood count, a metabolic panel and a B12 and folate. The Philadelphia laboratory performs the complete blood count, but the metabolic panel is performed at the Millville laboratory, while the B12 and folate is performed at the Boston Laboratory. The Pennsylvania carrier retains jurisdiction for processing the claims if they have certification information and the appropriate fee schedule allowance in house. Otherwise, the local carrier servicing Boston and/or Millville has jurisdiction for processing their claims.

EXAMPLE 3

Same relationships as in Example 2. American Laboratories, Inc., is an independent laboratory company with branch laboratories located in Philadelphia, PA and Wilmington, DE, as well as regional laboratories located in Millville, NJ and Boston, MA.

This time the Wilmington laboratory draws a blood specimen from a patient whose physician has ordered a blood culture. The Wilmington laboratory then sends the specimen to the Boston laboratory, which performs the required test. American Laboratories accepts an assignment for the service. If the carrier processing claims for providers/suppliers located in Delaware has the capability of comparing the Wilmington laboratory's charge for the blood culture against the appropriate reasonable charge screens for the Boston laboratory, the carrier processing claims for Delaware will retain jurisdiction for processing the claim. If the carrier processing claims for providers/suppliers located in Delaware does not have this capability, the claim should be transferred to the Massachusetts carrier for processing.

60 - Specimen Collection Fee and Travel Allowance

(Rev.)

B3-5114.1

60.1 - Specimen Collection Fee

(Rev.)

B3-5114.1, A3-3628

In addition to the amounts provided under the fee schedules, the Secretary shall provide for and establish a nominal fee to cover the appropriate costs in collecting the sample on

which a clinical laboratory test was performed and for which payment is made with respect to samples collected in the same encounter.

A specimen collection fee is allowed in circumstances such as drawing a blood sample through venipuncture (i.e., inserting into a vein a needle with syringe or vacutainer to draw the specimen) or collecting a urine sample by catheterization. A specimen collection fee is not allowed for blood samples where the cost of collecting the specimen is minimal (such as a throat culture or a routine capillary puncture for clotting or bleeding time). This fee will not be paid to anyone who has not extracted the specimen. Only one collection fee is allowed for each type of specimen for each patient encounter, regardless of the number of specimens drawn. When a series of specimens is required to complete a single test (e.g., glucose tolerance test), the series is treated as a single encounter.

60.1.1 - Physician Specimen Drawing

(Rev.)

HO-437, A3-3628, B3-5114.1

A specimen collection fee for physicians is allowed only when (1) it is the accepted and prevailing practice among physicians in the locality to make separate charges for drawing or collecting a specimen, and (2) it is the customary practice of the physician performing such services to bill separate charges for them.

60.1.2 - Independent Laboratory Specimen Drawing

(Rev.)

MCM 4110.4, HO-437, A3-3628

Separate charges made by laboratories for drawing or collecting specimens are allowable 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.

A specimen collection fee is allowed 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. A specimen collection fee is not allowed the visiting technician where 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 which 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 Chapter 15 of the Medicare Benefit Policy Manual §60.4 and §80.1.H respectively

for the definition 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 billing 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 §80.1.H, an educational contact with the prescribing physician is warranted and, where necessary, corroborating documentation 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.)

A3 3644.1, PR 2711.1, B3-4270.2, PUB-29 322

See Medicare Benefit Policy Manual, Chapter 11, "End Stage Renal Disease (ESRD)," §30.2, for a description of laboratory services included in the composite rate.

Independent laboratories and independent dialysis facilities with the appropriate clinical laboratory certification in accordance with CLIA may be paid for ESRD clinical laboratory tests that are separately billable. The laboratories and independent dialysis facilities are paid for separately billable clinical laboratory tests according to the Medicare laboratory fee schedule for independent laboratories. Independent dialysis facilities billing for separately billable laboratory tests that they perform must submit claims to the intermediary. Laboratories must bill the carrier.

Hospital-based laboratories providing laboratory service to hospital dialysis patients of the hospital's dialysis facility are paid in accordance with the outpatient laboratory provisions. However, where the hospital laboratory does tests for an independent dialysis facility or for another hospital's facility, the nonpatient billing provisions apply.

Clinical laboratory tests can be performed individually or in predetermined groups on automated profile equipment. A specimen collection fee up to $3 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 any patients dialyzed in the facility or for any patients dialyzed at home under reimbursement Method I. Payment for this service is included under the ESRD composite rate for separately billable laboratory tests as well as those included in the composite rate.

Fees for taking specimens from home dialysis patients, who have elected reimbursement Method II may be paid separately, provided all other criteria for payment are met. Also, 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.)

The following HCPCS codes and terminology must be used:

G0001 - Routine venipuncture for collection of specimen(s).

P96l5 - Catheterization for collection of specimen(s).

The allowed amounts are included in the laboratory fee schedule distributed annually by CMS.

60.2 - Travel Allowance

(Rev.)

HO-437, A3-3628.F, B4-5024, B3-5114.1; PM-AB-99-49

In addition to a specimen collection fee allowed under §60.1, a travel allowance is payable to cover the costs of collecting a specimen from a nursing home or homebound patient. The travel allowance is intended to cover the estimated travel costs of collecting a specimen and to reflect the technician's salary and travel costs.

The additional allowance can be made only where a specimen collection fee is also payable, i.e., no travel allowance is made where the technician merely performs a messenger service to pick up a specimen drawn by a physician or nursing home personnel. The travel allowance may not be paid to a physician unless the trip to the home, or to the nursing home was solely for the purpose of drawing a specimen. Otherwise travel costs are considered to be associated with the other purposes of the trip.

The travel allowance is not distributed by CMS. Instead the carrier must calculate the travel allowance for each claim using the following rules for the particular Code. The allowance is intended to cover the estimated travel costs of collecting a specimen and is

an allowance reflecting the technician's salary and travel costs. The following HCPCS codes are used for travel allowances:

P9603 - Travel allowance - one way, in connection with medically necessary laboratory specimen collection drawn from homebound or nursing home bound patient; prorated miles actually traveled (carrier allowance on per mile basis); or

P9604 - Travel allowance - one way, in connection with medically necessary laboratory specimen collection drawn from homebound or nursing home bound patient; prorated trip charge (carrier allowance on flat fee basis).

P9603 - Travel allowance

P9603 Example: The carrier determines that the average technician is paid $9 per hour and estimate 45 miles per hour as the average speed driven or $.20 per mile. Including the Federal allowance of $.25 per mile results in a total allowance of $.45 per mile. A laboratory technician makes a trip to two nursing homes involving a total of 20 miles and collects five specimens from Medicare and non-Medicare patients. A travel allowance per Medicare claim of $1.80 can be made - 20 miles round trip x $.45 per mile divided by 5 specimens. The supplier bills 4 miles (20 miles divided by 5) under code P9603.

P9603 (effective for claims submitted on or after October 1, 1998 for dates of service on or after January 1, 1998) - There is a minimum of 75 cents a mile. The per mile travel allowance is to be used in situations where the average trip to patients' homes is longer than 20 miles round trip, and is to be pro-rated in situations where specimens are drawn or picked up from non-Medicare patients in the same trip.

The per mile allowance was computed using the Federal mileage rate of 31 cents a mile plus an additional 44 cents a mile to cover the technician's time and travel costs. Contractors have the option of establishing a higher per mile rate in excess of the minimum of 75 cents a mile if local conditions warrant it. The minimum mileage rate will be reviewed and updated in conjunction with the clinical laboratory fee schedule, as necessitated by adjustments in the Federal travel allowance and salaries. Instructions for such updates and revisions will be sent to contractors through periodic administrative issuances. At no time will the laboratory be allowed to bill for more miles than are reasonable or for miles not actually traveled by the laboratory technician.

P9603 (10/1/98) Example 1: A laboratory technician travels 60 miles round trip from a laboratory in a city to a remote rural location, and back to the laboratory to draw a single Medicare patient's blood. The total reimbursement would be $45.00 (60 miles x .75 cents a mile), plus the specimen collection fee.

P9603 (10/1/98) Example 2: A laboratory technician travels 40 miles from the laboratory to a Medicare patient's home to draw blood, then travels an additional 10 miles to a non-Medicare patient's home and then travels 30 miles to return to the laboratory. The total miles traveled would be 80 miles. The claim submitted would be for one half of the miles traveled or $30.00 (40 x .75), plus the specimen collection fee.

P9604 Example: The carrier determines through a review of the laboratory records that on average, four specimens are drawn or picked up each trip and the average trip involves a 30 mile round trip. Assuming the same facts as Example 1 (i.e., $9 per hour and 45 miles per hour), the carrier establishes a flat travel allowance of $3.38. Suppliers bill code P9604 and are paid $3.38 regardless of actual distance or number of patients served.

P9604 - (effective for claims submitted on or after October 1, 1998 for dates of service on or after January 1, 1998) - There is a minimum of $7.50 one way. The flat rate travel allowance is to be used in areas where average trips are less than 20 miles round trip. The flat rate travel fee is to be pro-rated for more than one blood drawn at the same address, and for stops at the homes of Medicare and non-Medicare patients. The pro-ration is not done by the laboratory until the claim is submitted based on the number of patients seen on that trip. The specimen collection fee will be paid for each patient encounter.

This rate was based on an assumption that a trip is an average of 15 minutes and up to 10 miles one way. It uses the Federal mileage rate of 31 cents a mile and a laboratory technician's time of $17.66 an hour, including overhead. Contractors have the option of establishing a flat rate in excess of the minimum of $7.50 if local conditions warrant it. The minimum national flat rate will be reviewed and updated in conjunction with the clinical laboratory fee schedule, as necessitated by adjustments in the Federal travel allowance and salaries. Instructions for such updates and adjustments will be sent to contractors through periodic administrative issuances.

(10/1/98) Example 1: A laboratory technician travels from the laboratory to a single Medicare patient's home and returns to the laboratory without making any other stops. The flat rate would be calculated as follows: 2 x $7.50 for a total trip reimbursement of $15.00, plus the specimen collection fee.

(10/1/98) Example 2: A laboratory technician travels from the laboratory to the homes of five patients to draw blood, four of the patients are Medicare patients and one is not. An additional flat rate would be charged to cover the 5 stops and the return trip to the laboratory (6 x $7.50 =$45.00). Each of the claims submitted would be for $9.00 ($45.00/5 = $9.00). Since one of the patients is non-Medicare, four claims would be submitted for $9.00 each, plus the specimen collection fee.

(10/1/98) Example 3: A laboratory technician travels from a laboratory to a nursing home and draws blood from 5 patients and returns to the laboratory. Four of the patients are on Medicare and one is not. The $7.50 flat rate is multiplied by two to cover the return trip to the laboratory (2 x $7.50 = $15.00) and then divided by five (1/5 of $15.00 = $3.00). Since one of the patients is non-Medicare, four claims would be submitted for $3.00 each, plus the specimen collection fee.

If a carrier determines that it results in equitable payment, the carrier may extend the former payment allowances for additional travel (such as to a distant rural nursing home) to all circumstances where travel is required. This might be appropriate, for example, if the carrier's former payment allowance was on a per mile basis. Otherwise, it should

establish an appropriate allowance and inform the hospitals in its service area. If a carrier decides to establish a new allowance, one method is to consider developing a travel allowance consisting of:

- The current Federal mileage allowance for operating personal automobiles, plus a personnel allowance per mile to cover personnel costs based upon an estimate of average hourly wages and average driving speed.

Carriers must prorate travel allowance amounts claimed by suppliers by the number of patients (including Medicare and non-Medicare patients) from whom specimens were drawn on a given trip.

The carrier may determine that Payment in addition to the routine travel allowance determined under this section is appropriate for the additional costs of travel to collect a specimen from a nursing home or homebound patient when clinical laboratory tests are needed on an emergency basis outside the general business hours of the laboratory making the collection.

70 - Clinical Laboratory Improvement Amendments (CLIA) Requirements

(Rev.)

A3-628.2, RHC-640, ESRD 322, HO-306, HHA-465, SNF 541, HO-437.2, PM B-97-3

70.1 - Background

(Rev.)

A3-3628.2, PM B-97-4

The Clinical Laboratory Improvements Amendments of 1988 (CLIA), Public Law 100-578, amended §353 of the Public Health Service Act (PHSA) to extend jurisdiction of the Department of Health and Human Services to regulate all laboratories that examine human specimens to provide information to assess, diagnose, prevent, or treat any disease or impairment. The purpose of the CLIA program is to assure that laboratories testing specimens in interstate commerce consistently provide accurate procedures and services. As a result of CLIA, any laboratory soliciting or accepting specimens in interstate commerce for laboratory testing is required to hold a valid license or letter of exemption from licensure issued by the Secretary of HHS. The term "interstate commerce" means trade, traffic, commerce, transportation, or communication between any state, possession of the United States, the Commonwealth of Puerto Rico, or the District of Columbia, and any place outside thereof, or within the District of Columbia.

CLIA mandates that virtually all laboratories, including physician office laboratories (POLs), meet applicable Federal requirements and have a CLIA certificate in order to receive reimbursement from Federal programs. CLIA also lists requirements for

laboratories performing only certain tests to be eligible for a certificate of waiver or a certificate for Physician Performed Microscopy Procedures (PPMP). Since 1992, carriers have been instructed to deny clinical laboratory services billed by independent laboratories which did not meet the CLIA requirements. POLs were excluded from the 1992 instruction but included in 1997.

The CLIA number must be included on each Form CMS-1500 claim for laboratory services by any laboratory performing tests covered by CLIA.

70.2 - Billing

(Rev.)

The CLIA number is required in field 23 of the paper Form CMS-1500. The electronic formats have a field reserved for a CLIA number. See chapter 26 for specific reporting requirements.

70.3 - Verifying CLIA Certification

(Rev.)

A3-3628.2

Carrier claims are edited by CWF to ascertain that the laboratory identified by the CLIA number is certified to perform the test. (CWF uses data supplied from the certification process.) See the Medicare Claims Processing Manual, Chapter 27, for related specifications.

Providers that bill intermediaries are responsible for verifying CLIA certification prior to ordering laboratory services under arrangement. The survey process validates that these providers have procedures in place to insure that laboratory services are provided by CLIA approved laboratories.

70.4 - CLIA Numbers

(Rev.)

A3-3628.2D

The CLIA structure is:

Positions 1 and 2 is the State code (based on the laboratory's physical location at time of registration);

Position 3 is an alpha letter "D"; and

Positions 4-10 are unique numbers assigned by the CLIA billing system. (No other laboratory in the country has this number.)

Initially, providers are issued a CLIA number when they apply to the CLIA program. Independent dialysis facilities must obtain a CLIA certificate in order to perform clotting time tests.

70.5 - CLIA Categories and Subcategories

(Rev.)

A laboratory may be licensed or exempted from licensure in several major categories of procedures. These major categories are:

010	Histocompatibility
100	Microbiology
110	Bacteriology
115	Mycobacteriology
120	Mycology
130	Parasitology
140	Virology
150	Other Microbiology
200	Diagnostic Immunology
210	Syphilis Serology
220	General Immunology
300	Chemistry
310	Routine
320	Urinalysis
330	Endocrinology
340	Toxicology
350	Other
400	Hematology
500	Immuno-hematology

510	ABO Group and RH Type
520	Antibody Detection (Transfusion)
530	Antibody Detection (Non Transfusion)
540	Antibody Identification
550	Compatability Testing
560	Other
600	Pathology
610	Histopathology
620	Oral Pathology
630	Cytology
800	Radioassay
900	Clinical Cytogenics

For a list of specific HCPCS codes see http://www.cms.hhs.gov/clia/default.asp

70.6 - Certificate for Physician-Performed Microscopy Procedures

(Rev.)

A3-3628.2E

Effective January 19, 1993, a laboratory that holds a certificate for physician-performed microscopy procedures may perform only those tests specified as physician-performed microscopy procedures and waived tests, as described below, and no others.

HCPCS Code	Test
Q0111	Wet mounts, including preparations of vaginal, cervical or skin specimens
Q0112	All potassium hydroxide (KOH) preparations
Q0113	Pinworm examinations
Q0114	Fern test
Q0115	Post-coital direct, qualitative examinations of vaginal or cervical mucous
8101	Urine sediment examinations

70.7 - Deleted - held for expansion

(Rev.)

70.8 - Certificate of Waiver

(Rev.)

A3-3628.2F, PM AB-01-95

Effective September 1, 1992, all laboratory testing sites (except as provided in 42 CFR 493.3(b)) must have either a CLIA certificate of waiver or certificate of registration to legally perform clinical laboratory testing anywhere in the United States.

CLIA waived tests are identified by CMS and may change periodically. Some CLIA tests are implicitly waived based on procedure codes and some must have a QW modifier to be recognized as a waived test. Carriers are given the waived code revisions via a CMS issued Program Memo (PM) on a quarterly basis.

For a list of specific HCPCS codes subject to CLIA see
http://www.cms.hhs.gov/clia/default.asp

70.9 - CLIA License or Licensure Exemption

(Rev.)

CLIA mandates that virtually all laboratories, including Physician Office Laboratories (POLs), meet applicable Federal requirements and have a CLIA certificate in order to receive reimbursement from Federal programs. To receive a CLIA license or licensure exemption, an application form must be completed and signed by the laboratory's owner or authorized representative. A separate application must be filed for each laboratory location. If a laboratory changes location, the laboratory may either:

- Complete an initial application form, since it must be inspected and licensed at its new site; or

- Submit a statement from the laboratory director identifying the new location and the services the laboratory will offer in interstate commerce in lieu of an application form.

To obtain a copy of the application form see http://www.cms.hhs.gov/clia/default.asp

70.10 - CLIA Number Submitted on Form CMS-1500

(Rev.)

Effective with services provided October 1, 1997, any independent laboratory performing tests covered by CLIA must submit the CLIA number on the Form CMS-1500 hardcopy or electronic claim form. The CLIA number is reported in:

- Field 23 of the paper CMS-1500,

- Record FAO, field 34 of the NSF,

- ASC X12 837 (3051) REF segment as REF02, with qualifier of "X4" in REF01

- ASC X12 837 (4010) REF segment as REF02, with qualifier of "X4" in REF01

The CLIA number is not required on UB 92 or its related data sets.

See Chapter 25 for detailed format instructions.

Laboratory claims submitted without the CLIA number are returned as unprocessable. If the CLIA number is submitted on the claim, but is inconsistent with the CLIA format, the carrier will return the claim as unprocessable. If more than one CLIA number is submitted on the claim, except when a reference laboratory is on the same claim, the carrier will return the claim as unprocessable.

If the tests on one claim have been performed in more than one Physician Office Laboratory (POL) by the same physician, the appropriate CLIA number should be associated with the test that was performed in that laboratory. This will require that the physician submit a separate claim for each location (CLIA number) where a test was performed.

70.10.1 - Physician Notification of Denials

(Rev.)

If there is no CLIA number on the claim, the carrier sends RA messages MA 120 and MA 130 which state:

> MA 120 - Did not complete or enter accurately the CLIA number.
>
> MA 130 - Your claim contains incomplete and/or invalid information, and no appeal rights are afforded because the claim in unprocessable. Please submit the correct information to the appropriate intermediary or carrier.

70.11 - Reasons for Denial - Physician Office Laboratories Out-of-Compliance

(Rev.)

Carriers use remittance advice (RA) message B7 to notify the provider of the reason for denial. The B7 message states: This provider was not certified for this procedure/service on this date of service."

Carriers use MSN message #14.1, which states:

> The laboratory is not approved for this type of test.

80 - Issues Related to Specific Tests

(Rev.)

80.1 - Screening Services

(Rev.)

A3-3628.1, SNF 541.1, HO-437.1, RHC-437, CIM 50.20.1, PM AB-98-7, AB-98-22, B-98-16, A-98-6, R103.CIM MCM 4603.1

See Chapter 18, "Preventive Services and Vaccines" for payment, edit and MSN requirements for the following screening services.

A - Screening Pap Smear and Pelvic Examination

Effective January 1, 1998, Pap smears and screening pelvic examinations are covered under certain conditions. See the Benefit Policy Manual and the National Coverage Determinations manual for related coverage instructions.

B - Screening Prostate Tests

Effective for services furnished on or after January 1, 2000, Medicare covers prostate cancer screening tests and procedures for the early detection of prostate cancer. See the Benefit Policy Manual and the National Coverage Determinations manual for related coverage instructions.

C - Colorectal Cancer Screening

B3-4180, PM AB-97-24

Effective for services furnished on or after January 1, 1998, Medicare covers colorectal cancer screening test/procedures for the early detection of colorectal cancer. See the Benefit Policy Manual and the National Coverage Determinations manual for related coverage instructions.

80.2 - Anatomic Pathology Services

(Rev.)

Clinical laboratory tests include some services described as anatomic pathology services in CPT (i.e., certain cervical, vaginal, or peripheral blood smears). The CPT code 85060 is used only when a physician interprets an abnormal peripheral blood smear for a hospital inpatient or a hospital outpatient, and the hospital is responsible for the technical component. When a physician interpretation of an abnormal peripheral blood smear is billed by an independent laboratory, it is considered a complete or global service, and the service is not billed under the CPT code 85060. A physician interpretation of an abnormal peripheral blood smear performed by an independent laboratory is considered a routine part of the ordered hematology service (i.e., those tests that include a different white blood count).

HCPCS code 88150 (cervical or vaginal smears) included both screening and interpretation in CPT 1986 terminology while the CPT 1987 terminology includes only screening. A new code, 88151, was added for those smears which require physician interpretation. Code 88151 is treated and priced in the same manner as code 88150 was previously treated. Code 88151 with a "26" modifier is paid when a physician performs an interpretation of an abnormal smear for a hospital inpatient or outpatient, and the hospital is responsible for the technical component. The "26" modifier for code 88150 is no longer recognized. Code 88151(26) is priced as code 88150(26) would have been priced if the coding terminology had not been revised. Independent laboratories bill under code 88150 for normal smears and under code 88151 for abnormal smears. However, the fee schedule amount is equivalent.

80.2.1 - Technical Component (TC) of Physician Pathology Services to Hospital Patients

(Rev.)

PM AB-02-177

Section 542 of the Benefits Improvement and Protection Act of 2000 (BIPA) provides that the Medicare carrier can continue to pay for the TC of physician pathology services when an independent laboratory furnishes this service to an inpatient or outpatient of a covered hospital. This provision applies to TC services furnished during the 2-year period beginning on January 1, 2001.

For this provision, covered hospital means a hospital that had an arrangement with an independent laboratory that was in effect as of July 22, 1999, under which a laboratory furnished the TC of physician pathology services to fee-for-service Medicare beneficiaries who were hospital inpatients or outpatients and submitted claims for payment for the TC to a carrier. The TC could have been submitted separately or combined with the professional component and reported as a combined service.

The term "fee-for-service Medicare beneficiary" means an individual who:

1. Is entitled to benefits under Part A or enrolled under Part B of title XVIII or both; and

2. Is not enrolled in any of the following:

    a. A Medicare + Choice plan under Part C of such title;

    b. A plan offered by an eligible organization under §1876 of the Act;

    c. A program of all-inclusive care for the elderly under §1894 of the Act; or

    d. A social health maintenance organization demonstration project established under §4108(b) of the Omnibus Budget Reconciliation Act of 1987.

The following examples to illustrate the application of the statutory provision to arrangements between hospitals and independent laboratories.

In implementing §542, the carriers should consider as independent laboratories those entities that it has previously recognized and paid as independent laboratories.

An independent laboratory that has acquired another independent laboratory that had an arrangement on July 22, 1999, with a covered hospital, can bill the TC of physician pathology services for that hospital’s inpatients and outpatients under the physician fee schedule.

EXAMPLE 1

Prior to July 22, 1999, independent laboratory A had an arrangement with a hospital in which this laboratory billed the carrier for the TC of physician pathology services. In July 2000, independent laboratory B acquires independent laboratory A. Independent laboratory bills the carrier for the TC of physician pathology services for this hospital's patients in 2001 and 2002.

If a hospital is a covered hospital, any independent laboratory that furnishes the TC of physician pathology services to that hospital's inpatients or outpatients can bill the carrier for these services furnished in 2001 and 2002.

EXAMPLE 2:

As of July 22, 1999, the hospital had an arrangement with an independent laboratory, laboratory A, under which that laboratory billed the carrier for the TC of physician pathology service to hospital inpatients or outpatients. In 2001, the hospital enters into an arrangement with a different independent laboratory, laboratory B, under which laboratory B wishes to bill its carrier for the TC of physician pathology services to hospital inpatients or outpatients. Because the hospital is a "covered hospital," independent laboratory B can bill the carrier for the TC of physician pathology services to hospital inpatients or outpatients.

If the arrangement between the independent laboratory and the covered hospital limited the provision of TC physician pathology services to certain situations or at particular times, then the independent laboratory can bill the carrier only for these limited services.

An independent laboratory that furnishes the TC of physician pathology services to inpatients or outpatients of a hospital that is not a covered hospital may not bill the carrier for TC of physician pathology services furnished in 2001 or 2002.

An independent laboratory that has an arrangement with a covered hospital should forward a copy of this agreement or other documentation to its carrier to confirm that an arrangement was in effect between the hospital and the independent laboratory as of July 22, 1999. This documentation should be furnished for each covered hospital the independent laboratory services. If the laboratory did not have an arrangement with the covered hospital as of July 22, 1999, but has subsequently entered into an arrangement, then it should obtain a copy of the arrangement between the predecessor laboratory and the covered hospital and furnish this to the carrier. Until further notice, maintain a hard copy of this documentation for postpayment reviews.

The hospital cannot bill under the outpatient prospective system for the TC of physician pathology services if the independent laboratory that services that hospital outpatients is receiving payment from its carrier under the physician fee schedule.

80.3 - National Minimum Payment Amounts for Cervical or Vaginal Smear Clinical Laboratory Tests

(Rev.)

PM AB-99-84, AB-99-99

For cervical or vaginal smear clinical laboratory tests, payment is the lesser of the local fee or the national limitation amount, but not less than the "national minimum payment amount". However, in no case may payment for these tests exceed actual charges. The Part B deductible and coinsurance do not apply.

For tests performed on or after January 1, 2000, a national minimum payment amount of $14.60 is established and applies for cervical or vaginal smear clinical laboratory tests in accordance with §224 of the Balanced Budget Refinement Act (Public Law 106-113). The affected CPT laboratory test codes for the national minimum payment amount are 88142, 88143, 88144, 88145, 88147, 88148, 88150, 88152, 88153, 88154, 88164, 88165, 88166, 88167, G0123, G0143, G 0144, G0145, G0147, G0148 and P3000.

The minimum national payment amount will be reviewed and updated in conjunction with the clinical laboratory fee schedule, as required. Instructions for such updates will be sent to contractors through periodic administrative issuances.

80.4 - Oximetry

(Rev.)

B3-5114.1

Certain blood gas levels are determined either by invasive means through use of a blood specimen for a clinical laboratory test or by noninvasive means through ear or pulse oximetry which is not considered a clinical laboratory test. CPT code 82792 is used for invasive oximetry. HCPCS code M0592 is used for ear and pulse oximetry. Code M0592 is not subject to fee schedules.

90 - Automated Profile Tests and Organ/Disease Oriented Panels

(Rev.)

For the purposes of these instructions, the term "profile" or "panel" means a grouping of laboratory tests, which commonly is automatically performed on a single piece of testing equipment.

90.1 - Laboratory Tests Utilizing Automated Equipment

(Rev.)

B3-5114, HO-437, A3-3628

Clinical laboratory tests are covered under Medicare if they are reasonable and necessary for the diagnosis or treatment of an illness or injury. Because of the numerous technological advances and innovations in the clinical laboratory field and the increased availability of automated testing equipment, no distinction is generally made in determining payment for individual tests because of either (1) the sites where the service is performed, or (2) the method of the testing process used, whether manual or automated. Whether the test is actually performed manually or with automated equipment, the services are considered similar and the payment is the same.

However, where groups of tests that are billed individually may be done as a panel or profile, a determination must be made about whether payment should be made at the panel or profile rate.

90.1.1 - Automated Test Listing

(Rev.)

B3-5114, HO-437, A3-3628, PM AB-97-5, AB-97-7, AB-97-17

Profiles are specific groupings of blood chemistries which enable physicians to more accurately diagnose their patients' medical problems. While the component tests in automated profiles may vary somewhat from one laboratory to another, or from one physician's office or clinic to another, contractors group together those profile tests which can be performed at the same time on the same equipment to develop appropriate payment amounts. The carrier or intermediary must group together the individual tests in the profile when billed separately and consider the price of the related automated profile test. Payment cannot exceed the lower of the profile price or the totals of the prices of all the individual tests. (This rule is applicable also if the tests are done manually.) The profile HCPCS code and each individual test is priced at the lower of the billed charge or the fee amount; and the lower of the profile/panel price or the total of the prices for all covered components.

Payment is made only for those tests in an automated profile that meet Medicare coverage rules. Where only some of the tests in a profile of tests are covered, payment cannot exceed the amount that would have been paid if only the covered tests had been ordered. For example, the use of the 12-channel serum chemistry test to determine the blood sugar level in a proven case of diabetes is unreasonable because the results of a blood sugar test performed separately provide the essential information. Normally, the payment allowance for a blood sugar test is lower than the payment allowance for the automated profile of tests. In no event, however, may payment for the covered tests exceed the payment allowance for the profile.

However, price and pay the 1-22 automated multi-channel chemistry tests tested in §90.2 at the lowest possible amount in accordance with §90.3.

90.2 - Organ or Disease Oriented Panels

(Rev.)

B3-5114, HO-437, A3-3628

Organ or disease panels must be paid at the lower of the billed charge, the fee amount for the panel, or the sum of the fee amounts for all components. When panels contain 1 or more automated tests, determine the correct price for the panel by comparing the price for the automated profile laboratory tests with the sum of the fee amounts for individual tests. Payment for the total panel may not exceed the sum total of the fee amounts for individual covered tests. All Medicare coverage rules apply.

The carrier standard system must calculate the correct payment amount. The CMS furnishes fee prices for each code but the carrier system must compare individual codes billed with codes and prices for related individual tests. (With each HCPCS update, HCPCS codes are reviewed and the system is updated). Once the codes are identified, carriers publish panel codes to providers.

The only acceptable Medicare definition for the component tests included in the CPT codes for organ or disease oriented panels is the American Medical Association definition of component tests. All of the tests in the definition must be performed in order to bill using those panel codes. If the laboratory has a custom panel that includes other tests, in addition to those in the defined CPT or HCPCS panels, the additional tests, whether on the list of automated tests or not, are billed separately in addition to the CPT or HCPCS panel code if any of the CPT or HCPCS panel code(s) is/are billed.

NOTE: If a laboratory chooses, it can bill each of the component tests of these panels individually, but payment will be based upon the above rules.

TABLE OF CHEMISTRY PANELS

		Hepatic Function Panel *80076*	**Basic Metabolic** *80048*	**Comprehensive Metabolic** *80053*	**Renal Function Panel** *80069*	**Lipid* Panel** *80061*	**Electrolyte Panel** *80051*
Chemistry	**CPT Code**						
Albumin	82040	X		X	X		
Alkaline phosphatase	84075	X		X			
ALT (SGPT)	84460	X		X			

		Hepatic Function Panel *80076*	**Basic Metabolic** *80048*	**Comprehensive Metabolic** *80053*	**Renal Function Panel** *80069*	**Lipid* Panel** *80061*	**Electrolyte Panel** *80051*
Chemistry	**CPT Code**						
AST (SGOT)	84450	X		X			
Bilirubin, total	82247	X		X			
Bilirubin, direct	82248	X					
Calcium	82310		X	X	X		
Chloride	82435		X	X	X		X
Cholesterol	82465					X	
CK, CPK	82550						
CO2 (bicarbonate)	82374		X	X	X		X
Creatinine	82565		X	X	X		
GGT	82977						
Glucose	82947		X	X	X		
LDH	83615						
Phosphorus	84100				X		
Potassium	84132		X	X	X		X
Protein, total	84155	X		X			
Sodium	84295		X	X	X		X
Triglycerides	84478					X	
Urea nitrogen (BUN)	84520		X	X	X		
Uric Acid	84550						

90.3 - Claims Processing Requirements for Panel and Profile Tests

(Rev.)

PM AB-97-17

All test codes should be processed and stored in history as they are submitted. That is, if tests are submitted as individual CPT codes together and paid as a panel, the claim history data will reflect the individual codes and the panel used in pricing. All tests must maintain their identity as billed.

Prior to January 1, 1998, automated panel codes were adjudicated only on a line by line basis with application of the correct coding initiative (CCI) edits for duplicate detection.

Beginning with processing date January 1, 1998, when individual automated test codes are received, carriers and intermediaries do not combine them into panels for processing. The only instance in which they should be panel codes is when they are coded as such on the claim.

Panels must be processed line by line, and must be compared to other claims with automated test panels and/or single laboratory HCPCS codes in the current processing cycle, plus previous paid/processed claims. Therefore, any and all automated tests must be paid as a panel, but still retain their individual identity for duplicate detection and medical necessity review.

Carriers and Intermediaries

1. Deny Duplicates. Deny duplicate services detected within the same processing cycle or stored in an automated history file. Consider claims that match on the following items as duplicates

a. The service was performed by the same provider,

b. For the same beneficiary, and

c. For the same date of service.

2. Medical Necessity. Determine medical necessity. This process permits the identification of CPT codes subject to local medical review policies.

3. Process Claims. The processes shown below (A-H) should be followed to price and pay claims for automated panels (as defined in HCPCS) and individual tests. This does not replace or abridge any current procedures in place concerning the adjudication of claim. This is a general procedure for combining these services to attain the lowest pricing outcome. This display is an example only. System maintainers have the flexibility to vary these procedures as long as they attain the same result.

A. Unbundle all panels to single lines representing individual automated tests, and identify duplicate tests within the claim. On concurrently processed claims, the total amount payable must be determined based on the combination of all tests billed by the same laboratory for the same date of service.

B. Check history for automated laboratory services provided on the same day, same beneficiary, and the same provider. Unbundle any panels. Identify duplicate services. Aggregate all nonduplicate services for pricing (include the submitted charge and paid amounts for both individually or paneled billed claims). If a single organ disease panel or a single chemistry panel contains the only automated test claims for that date of service, adjudicate as billed.

C. Compare each line's submitted charge to the fee schedule for that code (including automated tests retrieved from history).

D. Sum the comparisons of the line by line.

E. Obtain the fee for all automated tests as a panel including all services in history. If organ disease (OD) panels are involved, this would include fees for nonautomated test included in the OD panel.

F. Carry forward the lesser of items D or E.

G. Subtract from item F any previous automated laboratory test (individual or paneled) or organ disease panel containing automated tests payments. If nothing is payable on the claim, it must still be allowed with no payment (a zero pay claim allowance and common working file (CWF) must allow these claims into their process).

H. The amount payable is the total payable based on the combination of current and previously processed claims, less the total amount paid on the previous claim(s).

I. If a claim is a Clinical Laboratory Improvement Act (CLIA) reject from the CWF, the claims process should then recycle that claim through the payment process to recalculate payment.

90.3.1 - History Display

(Rev.)

When displaying claims payment for each CPT code in history, contractors apply the following rules:

1. If all component tests of any panel are allowed because the individual line item comparison is less than the fee (item D above is less than item E), record the panel codes as determined on the line by line comparison.

2. If all component tests are paid based on the panel price, allocate the current payment proportionate to the amount submitted for each CPT code.

3. If any panel tests will be denied or there are previously paid automated laboratory tests (as indicated by a check of beneficiary history), allocate the current payment amount by allowed line proportionate to what was submitted for the current claim being processed.

For administration of pricing requirements and/or invalid coding policies, contractors must establish a processing sequence for concurrently processed claims based on ascending order of internal control number (ICN). In the case of pricing, they must process the "first claim" (i.e., lower CN) based solely on the billed codes on that claim, process the "second" claim based on a combination of the billed codes on both claims and pay the balance due after subtracting the amount paid on the "first" claim. In the case of unacceptable code combinations, contractors must deny the "second" claim.

90.3.2 - Medicare Secondary Payer

(Rev.)

When processing claims involving Medicare secondary payer (MSP), carriers should use the MSP payment formula as follows:

When Medicare is secondary, Medicare pays the lowest of:

- The actual charge less the primary payment;
- The amount Medicare would pay if primary; or
- The higher of the Medicare or primary allowable less the primary payment.

The two-step pricing comparison described above is required for calculating MSP amounts.

90.4 - Evaluating the Medical Necessity for Laboratory Panel CPT Codes

(Rev.)

PM-B-98-1

The American Medical Association's (AMA) 1998 edition of the Current Procedural Terminology (CPT) establishes three new and one revised Organ or Disease Oriented laboratory panels. Since these panels are composed of clinically relevant groupings of automated multi-channel tests there is a general presumption of medical necessity. If there is data or reason to suspect abuse of the new panel codes, contractors may review these claims. Should a contractor determine the need to develop a local medical review policy for laboratory panel codes, the contractor should develop these policies at the

panel code level. In some instances of perceived abuse of the new panel codes, a contractor may review the panel and deny component tests on a case-by-case basis or evaluate the need for the component level test.

90.5 - Special Processing Considerations

(Rev.)

PM AB-97-17

To order any of the 22 automated tests, a physician may select individual tests or the panel. A physician may order a mix of panels and individual tests. The physician should review what tests are in each panel and not order individual tests which might duplicate tests in the panel. Any duplicate tests will be denied by Medicare.

Specialists are not restricted to ordering certain panels or individual tests because of their specialty. The physician (general practitioner or specialist) should identify which tests he/she wishes to have and if they match a grouping, and then order the appropriate panel. Any other tests that are not included in a panel should be separately billed.

It is appropriate to use the QP modifier with the single ordering of tests or when a single code is available for groupings of tests.

100 - CPT Codes Subject to and Not Subject to the Clinical Laboratory Fee Schedule

(Rev.)

HO-437, A3-3628, B3-5114.1

For purposes of the fee schedule, clinical laboratory services include most laboratory tests listed in codes 80048-89399 of the Current Procedural Terminology Fourth Edition, 1996 printing, (CPT-1996). The CMS issues an update to the laboratory fee schedule each year, with information about whether prices have been determined by CMS or whether the individual carrier must determine the allowable charge.

Codes not included are not paid under the laboratory fee schedule but may be paid under the MPFS if covered for Medicare.

100.1 - Deleted-Held for expansion

(Rev.)

100.2 - Laboratory Tests Never Subject to the Fee Schedule

(Rev.)

Some CPT codes in the 80000 series are not clinical laboratory tests and are therefore never subject to fee schedule limitations. Some of these codes are exempted because they are not clinical laboratory services. They include codes for procedures, services, blood products and auto-transfusions. They include codes such as whole blood, various red blood cell products, platelets, plasma, and cryoprecipitate. Other codes for tests primarily associated with the provision of blood products are also not considered to be clinical tests. Such tests identify various characteristics of blood products, but are not diagnostic in nature. These include various blood cross matching techniques. Exclusion codes are paid under the MPFS, reasonable charges, reasonable costs, or OPPS as applicable if they are covered.

100.3 - Procedures Not Subject to Fee Schedule When Billed With Blood Products

(Rev.)

The following codes are not subject to fee schedule limitations when submitted for payment on the same bill with charges for blood products. In that case, they are assumed to be used for blood matching and not for diagnostic purposes.

Codes: 86901, 86905, 86930-86932, 86920-86922, 86890, 86870, 86891, 86880-86886, 86971, and 86930.

If no blood product is provided and billed for on the same claim, the codes are assumed to be diagnostic and are subject to the clinical laboratory fee schedule.

The standard system is expected to provide for this processing.

100.4 - Not Otherwise Classified Clinical Laboratory Tests

(Rev.)

The following codes for unlisted or not otherwise classified (NOC) clinical laboratory tests are not subject to the NLA:

81099 87999

84999 88299

85999 89399

86999

NOC codes shall suspend for review and the carrier shall determine a price for them.

100.5 - Other Coding Issues

(Rev.)

100.5.1 - Tests Performed More Than Once on the Same Day

(Rev.)

PM AB-98-7

Modifier 59 or 91 are used to indicate that a test was performed more than once on the same day for the same patient when it is necessary to obtain multiple results in the course of treatment. The 91 modifier is used for laboratory tests paid under the clinical laboratory fee schedule.

These modifiers may be used to indicate that a test was performed more than once on the same day for the same patient, only when it is necessary to obtain multiple results in the course of treatment. These modifiers may not be used when tests are rerun to confirm initial results; due to testing problems with specimens and equipment; or for any other reason when a normal, one-time, reportable result is all that is required. These modifiers may not be used when there are standard HCPCS codes available that describe the series of results (e.g. glucose tolerance tests, evocative/suppression testing, etc.). This modifier may only be used for laboratory tests paid under the clinical laboratory fee schedule.

Improper use of modifiers are likely to indicate a fraudulent or abusive circumstance. When informing laboratories of the availability of modifiers, carriers are to emphasize that these modifiers have very narrow application and that any evidence of excessive use will be referred to Carrier/Intermediary Program Integrity Unit for further review.

100.6 - Pricing Modifiers

(Rev.)

PM A-03-033

Three pricing modifiers discretely identify the different payment situations for ESRD Automated Multi-Channel Chemistry (AMCC) tests. The physician that orders the tests is responsible for identifying the appropriate modifier when ordering the tests. The modifiers are in the following listing:

- CD - AMCC test has been ordered by an ESRD facility or MCP physician that is part of the composite rate and is not separately billable

- CE - AMCC test has been ordered by an ESRD facility or MCP physician that is a composite rate test but is beyond the normal frequency covered under the rate and is separately reimbursable based on medical necessity

- CF - AMCC test has been ordered by an ESRD facility or MCP physician that is not part of the composite rate and is separately billable

ESRD clinical laboratory tests identified with modifiers "CD", "CE" or "CF" may not be billed as organ or disease panels. Effective October 1, 2003, all ESRD clinical laboratory tests must be billed individually.

110 - Coordination Between Carriers and Other Entities

(Rev.)

B3-5114.1

110.1 - Coordination Between Carriers and Intermediaries/RRB

(Rev.)

The carrier furnishes copies of fees that are locally established under the fee schedules (price code = 22) to Medicare fiscal intermediaries and to the appropriate Railroad Retirement Board (RRB) carrier. The carrier must provide updates at least 30 days prior to the scheduled implementation. The fiscal intermediaries add these fees to system fee schedule tables to use in paying for hospital laboratory tests performed for outpatients of the hospital and for persons who are not patients of the hospital. The RRB contractor uses the fee schedules in paying for outpatient clinical laboratory tests.

Intermediaries and the RRB may consult with carriers on filling gaps in fee schedules for tests where the carrier may not have established an amount. If intermediaries or the RRB carrier has bills for payment on laboratory tests for which the carrier has not furnished amounts, they consult with the area carrier. If necessary the area carrier will consult with other nearby carriers.

110.2 - Coordination With Medicaid

(Rev.)

Carriers furnish copies of the fee schedules and the annual update (including national limitation amounts where applicable) to State agencies. Carriers provide updates at least 30 days prior to the scheduled implementation. To obtain Federal matching funds for clinical laboratory services, State Medicaid agencies may not pay more for the services and specimen collections than are paid for them under Medicare. This applies to payments for calendar quarters beginning on or after October 1, 1984.

Since the fee schedule provisions have been implemented on a carrierwide basis, a State may have more than one carrier servicing Medicare beneficiaries residing in the State. A

Medicaid agency for such a State may, if it deems necessary, use the fee schedules of either one or both of the carriers to meet the Federal fund matching requirement. State Medicaid agencies may consult with ROs concerning the fee schedule, the national limitation amounts, and specimen collection provisions.

110.3 - Coordination With Intermediaries and Providers

(Rev.)

HO-437, A3-3628

There may be procedures for which hospitals bill for outpatients that are not included in the fee schedule. Where gaps occur, hospitals should work out procedures with the intermediary so that the hospital can secure the missing information promptly. Price Codes which are established by the carrier to fill gaps are valid until replaced by the earlier of permanent codes or the next annual update.

110.4 - Carrier Contacts With Independent Clinical Laboratories

(Rev.)

B3-2070.1.F

An important role of the carrier is as a communicant of necessary information to independent clinical laboratories. Failure to inform laboratories of Medicare regulations and claims processing procedures may have an adverse effect on prosecution of laboratories suspected of fraudulent activities with respect to tests performed by, or billed on behalf of, independent laboratories. United Stated Attorneys often have to prosecute under a handicap or may simply refuse to prosecute cases where there is no evidence that a laboratory has been specifically informed of Medicare regulations and claims processing procedures.

To assure that laboratories are aware of Medicare regulations and carrier's policy, notification must be sent to independent laboratories when any changes are made in coverage policy or claims processing procedures. Additionally, to completely document efforts to fully inform independent laboratories of Medicare policy and their responsibilities, previously issued newsletters should be periodically re-issued to remind laboratories of existing requirements.

Some items which should be discussed are the requirements to have the same charges for Medicare and private patients, to document fully the medical necessity for collection of specimens from a skilled nursing facility or a beneficiary's home, and, in cases when a laboratory service is referred from one independent laboratory to another independent laboratory, to identify the laboratory actually performing the test.

Additionally, when carrier professional relations representatives make personal contacts with particular laboratories, they should prepare and retain reports of contact indicating dates, persons present, and issues discussed.

120- Clinical Laboratory Services Based on the Negotiated Rulemaking

(Rev.)

PM AB02-129

Section 4554(b)(1) of the Balanced Budget Act (BBA), Public Law 105-33 mandated the use of a negotiated rulemaking committee to develop national coverage and administrative policies for clinical laboratory services payable under Part B of Medicare. The BBA required that these national policies be designed to promote program integrity and national uniformity and simplify administrative requirements with respect to clinical diagnostic laboratory services payable under Part B.

These changes apply to every diagnostic clinical laboratory service that is payable under Medicare Part B. Neither the place where the service was performed, nor the type of contractor that will process the request for payment, has any effect on the applicability of these policies. A clinical laboratory service done in a hospital laboratory, independent laboratory, physician/practitioner office laboratory or other type of CLIA approved laboratory service is subject to these administrative policies.

The final rule did not supercede the requirement that all physician claims must have a diagnosis. If a physician submits a claim for a service performed in a physician office laboratory, that claim is considered a physician claim and must meet the requirements for physician claims.

120.1 - Negotiated Rulemaking Implementation

(Rev.)

Date of Service

The following requirements apply to service providers:

- The date of service should be reported as the date of specimen collection.
- The person obtaining the specimen must furnish the date of collection for the specimen to the entity billing Medicare.
- For specimen collections that span more than a 24-hour period, the date of service should be reported as the date the collection began.
- For laboratory tests that require a specimen from stored collections, the date of service should be defined as the date the specimen was obtained from the archives.
- If a situation occurs that does not correspond to the two situations described, the contractor will submit, to the regional office, the question with the appropriate

documentation. The regional office will contact the Division of Supplier Claims Processing in CMS, who will serve as the point of contact.

Matching of Diagnosis to Procedure

During claims processing and adjudication, the contractor adheres to the following:

If there is a LMRP or NCD for one or more of the services included on the claim, the contractor reviews all of the diagnosis codes in making a determination regarding medical necessity of the service.

Even though a claim matches diagnosis to procedure in accordance with an NCD, other rules of adjudication may apply, which could result in denial.

Diagnoses are not required on claims for laboratory services from hospitals or independent laboratories unless there is a national coverage determination (NCD) for the service, the contractor has a local medical review policy (LMRP) for the service, or the contractor has notified the provider of the need for diagnoses on their claims due to medical review. Physicians who submit claims for tests done in a physician office laboratory are still subject to the requirement for an ICD-9 diagnosis on a claim.

Clarification of the Use of the Term "Screening" or "Screen"

The final rule clarifies that effective, February 21, 2002, the use of the term "screening" or "screen" in CPT code descriptor does not necessarily describe a test performed in the absence of signs and symptoms of illness, disease or condition. Contractors do not deny a service based solely on the presence of the term "screening" or "screen" in the descriptor.

Tests that are performed in the absence of signs, symptoms, complaints, personal history of disease, or injury are not covered except when there is a statutory provision that explicitly covers tests for screening as described.

If a person is tested to rule out or to confirm a suspected diagnosis because the patient has a sign and/or symptoms, this is considered a diagnostic test, not a screening test. Contractors have discretionary authority to make reasonable and necessary scope of benefit determinations.