Medicare Claims Processing Manual

Chapter 16 - Laboratory Services

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10.1 - Definitions

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

"Independent Laboratory" - An independent laboratory is one that is independent both of an attending or consulting physician's office and of a hospital that 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, for detailed discussion.)

"Physician Office Laboratory" – A physician office laboratory is a laboratory maintained by a physician or group of physicians for performing diagnostic tests in connection with the physician practice.

"Clinical Laboratory" - See the Medicare Benefits Policy Manual, Chapter 15.

"Qualified Hospital Laboratory" - A qualified hospital laboratory is one that provides some clinical laboratory tests 24 hours a day, 7 days a week, to serve a hospital's emergency room that is also available to provide services 24 hours a day, 7 days a week. For the qualified hospital laboratory meet this requirement, the 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; and hospital laboratory technologists must be on duty or on call at all times to provide testing for the emergency room.

"Hospital Outpatient" - See the Medicare Benefit Policy Manual, Chapter 2.

"Referring laboratory" - *A Medicare-approved laboratory that receives a specimen to be tested and that refers the specimen to another laboratory for performance of the laboratory test.*

"Reference laboratory" - *A Medicare-enrolled laboratory that receives a specimen from another, referring laboratory for testing and that actually performs the test.*

"Billing laboratory" - *The laboratory that submits a bill or claim to Medicare.*

"Service" - *A clinical diagnostic laboratory test. Service and test are synonymous.*

"Test" - *A clinical diagnostic laboratory service. Service and test are synonymous.*

"CLIA" - *The Clinical Laboratories Improvement Act and CMS implementing regulations and processes.*

"Certification" - *A laboratory that has met the standards specified in the CLIA.*

"Draw Station' - *A place where a specimen is collected but no Medicare-covered clinical laboratory testing is performed on the drawn specimen.*

"Medicare-approved laboratory - *A laboratory that meets all of the enrollment standards as a Medicare provider including the certification by a CLIA certifying authority.*

40.1 - Laboratories Billing for Referred Tests

(Rev. 23, 10-31-03)

B3-5114.1.E,

Section 1833(h)(5)(A) of the Act provides that a referring laboratory may bill for clinical laboratory diagnostic tests on the clinical laboratory fee schedule for Medicare beneficiaries performed by a reference laboratory only if the referring laboratory meets certain conditions. Payment may be made to the referring laboratory but only if one of the following conditions is met:

- 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; or
- the referring laboratory does not refer more than 30 percent of the clinical laboratory tests for which it receives requests for testing during the year (not counting referrals made under the wholly-owned condition described above).

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

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 tests referred to a non-related laboratory are counted. Thus, 30.5 percent (61/200) of the tests are considered tests referred to a non-related laboratory and, since this exceeds the 30 percent standard, the referring laboratory may not bill for any Medicare beneficiary laboratory tests referred to a non-related laboratory.

(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. Since this is less than 30 percent, the referring laboratory may bill for all tests.

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. The RO shall take whatever action is necessary to correct the problem.

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

NOTE: Laboratory services provided to a SNF inpatient under Part A are billed by the SNF, not the laboratory, due to consolidated billing for SNFs.

Only one laboratory may bill for a referred laboratory service. It is the responsibility of the referring laboratory to ensure that the reference laboratory does not bill Medicare for the referred service when the referring laboratory does so (or intends to do so). In the event the reference laboratory bills or intends to bill Medicare, the referring laboratory may not do so.

40.1.1 Claims Information and Claims Forms & Formats

Claims for referred laboratory services may be made only by suppliers having specialty code 69, i.e., independent clinical laboratories. Claims for referred laboratory services made by other entities will be returned as unprocessable.

Independent laboratories shall use modifier 90 to identify all referred laboratory services. A claim for a referred laboratory service that does not contain the modifier 90 is returned as unprocessable if the claim can otherwise be identified as being for a referred service.

The name, address, and CLIA number of both the referring laboratory and the reference laboratory shall be reported on the claim.

40.1.1.1 - Paper Claim Submission To Carriers

An independent clinical laboratory that elects to file a paper claim form shall file Form CMS-1500 for a referred laboratory service (as it would any laboratory service).

An independent clinical laboratory that submits claims in paper format) may not combine non-referred (i.e., self-performed) and referred services on the same CMS 1500 claim form. When the referring laboratory bills for both non-referred and referred tests, it shall submit two separate claims, one claim for non-referred tests, the other for referred tests. If billing for services that have been referred to more than one laboratory, the referring laboratory shall submit a separate claim for each laboratory to which services were referred. (unless one or more of the reference laboratories are separately billing Medicare). A paper claim that contains both non-referred and referred tests is returned as unprocessable.

When the referring laboratory is the billing laboratory, the reference laboratory's name and address shall be reported in item 32 on the CMS-1500 claim form to show where the service (test) was actually performed Also, the CLIA number of the reference laboratory shall be reported in item 23 on the CMS-1500 claim form. A paper claim that does not have the name and address of the reference laboratory in item 32 or the CLIA number of the reference laboratory in item 23 is returned as unprocessable.

> ***Example:*** *A physician has ordered the ABC Laboratory to perform carcinoembryonic antigen (CEA) and hemoglobin testing for a patient. Since the ABC Laboratory is approved to perform tests only within the hematology LC level (which includes the hemoglobin test), it refers the CEA testing (which is a routine chemistry LC) to the XYZ laboratory.*
>
> ***Result:*** *The ABC laboratory submits a claim for the hemoglobin test and reports its CLIA number in item 23 on the CMS-1500 form. Since the ABC laboratory referred the CEA test to the XYZ laboratory to perform, the ABC laboratory (billing laboratory) submits a second claim for the CEA testing, reporting XYZ's CLIA number in item 23 on the CMS-1500 form. The XYZ laboratory's name, and address is also reported in item 32 on Form CMS-1500 to show where the service (test) was actually rendered. The address where the services were performed should be entered should be entered in block 32 if it is different from the address in block 33.*

40.1.1.2 - Electronic Claim Submission to Carriers

Electronic Claim Submission

> *American National Standards Institue (ANSI) X12N 837 (HIPAA version) format electronic claims:*
>
> *CLIA number:*
>
> *An ANSI claim for laboratory testing will require the presence of the performing (and billing) laboratory's CLIA number; if tests are referred to another laboratory, the CLIA number of the laboratory where the testing is rendered must also be on the claim. An ANSI electronic claim for laboratory testing must be submitted using the following format:*

- *ANSI Electronic claim: the billing laboratory performs all laboratory testing.*

The independent laboratory submits a single claim for CLIA-covered laboratory tests and reports the billing laboratory's number in:

X12N 837 (HIPAA version) loop 2300, REF02. REF01 = X4

- *ANSI Electronic claim: billing laboratory performs some laboratory testing; some testing is referred to another laboratory.*

The ANSI electronic claim will not be split; CLIA numbers from both the billing and reference laboratories must be submitted on the same claim. The presence of the '90' modifier at the line item service identifies the referral tests. Referral laboratory claims are only permitted for independently billing clinical laboratories, specialty code 69.

The billing laboratory submits, on the same claim, tests referred to another (referral/rendered) laboratory, with modifier 90 reported on the line item and reports the referral laboratory's CLIA number in:

X12N 837 (HIPAA version) loop 2400, REF02. REF01 = F4

Example: A physician has ordered the DEF independent laboratory to perform glucose testing and tissue typing for a patient. Since the DEF Laboratory is approved to perform only at the routine chemistry LC level (which includes glucose testing), it refers the tissue-typing test to the GHI laboratory.

The DEF laboratory submits a single claim for the glucose and tissue typing tests; the line item service for the glucose test is submitted without a '90' modifier since the DEF laboratory performed this test. The CLIA number for the DEF laboratory is entered in the electronic claim in:

X12N 837 (HIPAA version) loop 2300, REF02. REF01 = X4

On the same claim, the line item service for the tissue typing test is submitted with a '90' modifier and the referral/rendering GHI laboratory's CLIA number is entered on the electronic claim in:

X12N 837 (HIPAA version) loop 2400, REF02. REF01 = F4

Reference Laboratory's Address

An electronic claim for laboratory testing requires the presence of the performing and billing laboratory's, name and address. The performing laboratory for a service with a line item CPT 90 modifier requires provider information for the X12N 837 in Loop 2420C.

National Standard Format (NSF) Electronic Claims:

CLIA number:

An NSF claim for laboratory testing will require the presence of the performing (and billing) laboratory's CLIA number: if tests are referred to another laboratory, the CLIA number of the laboratory where the testing is rendered must be on the claim. An NSF electronic claim for laboratory testing must be submitted using the following format:

The electronic claim will not be split; CLIA numbers from both the billing and reference laboratories must be submitted on one claim. The presence of the '90' modifier at the line item identifies the referral tests The CLIA number

reported on line items with modifier 90 will be the CLIA number of the performing clinical diagnostic laboratory. Referral laboratory claims are only permitted for independently billing clinical laboratories, specialty code 69. The CLIA number shall be reported in:

FA0 – 34.0

Reference Laboratory's Address

An NSF electronic claim for laboratory testing requires the presence of the performing and billing laboratory's, name and address. The performing laboratory for a service with a line item CPT '90' modifier requires provider information to be submitted in the following NSF record and fields:

FB0 – 27.0 Name
FB0 – 28.0 Address 1
FB0 – 29.0 Address 2
FB0 – 30.0 City
FB0 – 12.0 State
FB0 – 31.0 Zip

50.1 - Referring Laboratories

(Rev. 23, 10-31-03)

B3-5114.1

Medicare recognizes that specimens drawn or collected by one laboratory are sometimes referred to another laboratory for testing. Payment for a Medicare-covered, referred laboratory service may be made under the rules established in Chapter 15 §40.1.

The rules specified Chapter 15 §40.1 do not apply to services performed in a physician office laboratory or a qualified hospital laboratory. Both circumstances are entirely outside the scope of all sections concerning referral laboratory services.

Every carrier shall process a claim for a referred laboratory service if submitted by an independent clinical laboratory with a physical presence within the carrier's jurisdiction, notwithstanding that the referred laboratory service may have been performed outside of its jurisdiction.

Every carrier shall maintain the clinical laboratory fee schedules for each carrier jurisdiction and be able to process claims using those fee schedules.

Every carrier shall base payment for a referred service on the fee schedule for the jurisdiction in which the service was performed, i.e., where the test was performed. An exception to this rule allows a payment for a service that is carrier-priced to be based upon the price developed by the carrier processing the claim.

Every carrier that has previously assigned "reference use only" PINs to out-of-jurisdiction laboratories for the purpose of their billing referred services shall cancel such "reference-use-only" PINs.

Carriers must use the numerical locality codes specified in 50.4 to identify the appropriate clinical diagnostic laboratory fee schedule for use in pricing a referred laboratory service.

50.4 - Reporting of Pricing Localities for Clinical Laboratory Services

(Rev. 23, 10-31-03)

PM-B-97-12

Carriers shall report to the common working file (CWF) new State pricing localities (positions 58 and 59 on the carrier record) indicated on the Clinical Diagnostic Laboratory fee schedule for any reference laboratory service billed with a HCPCS 90 modifier. If the laboratory test billed is not a reference laboratory service, the Carrier Locality (location 11-12) on the Clinical Diagnostic Laboratory fee schedule should be forwarded to the CWF. For dates of service on or after April 1, 2004, CWF will not edit clinical laboratory pricing locality.

The carrier and intermediary record layouts, plus the State pricing locations are as follows:

CARRIER RECORD LAYOUT FOR DATA FILE
CLINICAL LABORATORY FEE SCHEDULE

Data Element Name	*Picture*	*Location*	*Comment*
HCPCS Code	*X(05)*	*1-5*	
Carrier Number	*X(05)*	*6-10*	
Carrier Locality	*X(02)*	*11-12*	*00--Single State Carrier* *01--North Dakota* *02--South Dakota* *20--Puerto Rico*
60% Local Fee	*9(05)V99*	*13-19*	
62% Local Fee	*9(05)V99*	*20-26*	
60% Natl Limit Amt	*9(05)V99*	*27-33*	
62% Natl Limit Amt	*9(05)V99*	*34-40*	
60% Pricing Amt	*9(05)V99*	*41-47*	
62% Pricing Amt	*9(05)V99*	*48-54*	
Gap-Fill Indicator	*X(01)*	*55-55*	*0--No Gap-fill Required* *1--Carrier Gap-fill* *2--Special Instructions Apply*
Modifier	*X(02)*	*56-57*	*Where modifier is shown, QW denotes a CLIA waiver Test.*
State Locality	*X(02)*	*58-59*	*See attached*
FILLER	*X(01)*	*60*	

INTERMEDIARY RECORD LAYOUT FOR DATA FILE
CLINICAL LABORATORY FEE SCHEDULE

Data Element Name	*Picture*	*Location*	*Comment*
HCPCS	*X(05)*	*1-5*	
Filler	*X(04)*	*6-9*	
60% Pricing Amt	*9(05)V99*	*10-16*	
62% Pricing Amt	*9(05)V99*	*17-23*	
Filler	*X(07)*	*24-30*	
Carrier Number	*X(05)*	*31-35*	
Carrier Locality	*X(02)*	*36-37*	*00--Single State Carrier* *01--North Dakota* *02--South Dakota* *20--Puerto Rico*
State Locality	*X(02)*	*38-39*	*See Attached*
FILLER	*X(21)*	*40-60*	

CarrierLocality/StateLocality Map

Carrier/Loc 0051000=StateLoc 01 (ALABAMA)
Carrier/Loc 0051100=StateLoc 02 (GEORGIA)
Carrier/Loc 0051200=StateLoc 03 (MISSISSIPPI)
Carrier/Loc 0052000=StateLoc 04 (ARKANSAS)
Carrier/Loc 0052100=StateLoc 05 (NEW MEXICO)
Carrier/Loc 0052200=StateLoc 06 (OKLAHOMA)
Carrier/Loc 0052300=StateLoc 07 (MISSOURI GENERAL AMERICAN)
Carrier/Loc 0052800=StateLoc 08 (LOUISIANA)
Carrier/Loc 0059000=StateLoc 09 (FLORIDA)
Carrier/Loc 0059100=StateLoc 10 (CONNECTICUT)
Carrier/Loc 0063000=StateLoc 11 (INDIANA)
Carrier/Loc 0065000=StateLoc 12 (KANSAS)
Carrier/Loc 0065500=StateLoc 13 (NEBRASKA)
Carrier/Loc 0066000=StateLoc 14 (KENTUCKY)
Carrier/Loc 0074000=StateLoc 15 (MISSOURI)
Carrier/Loc 0075100=StateLoc 16 (MONTANA)
Carrier/Loc 0080100=StateLoc 17(WESTERN NEW YORK)
Carrier/Loc 0080300=StateLoc 18 (EMPIRE NEW YORK)
Carrier/Loc 0080500=StateLoc 19 (NEW JERSEY)
Carrier/Loc 0082001=StateLoc 20 (NORTH DAKOTA)
Carrier/Loc 0082002=StateLoc 21(SOUTH DAKOTA)
Carrier/Loc 0082400=StateLoc 22 (COLORADO)
Carrier/Loc 0082500=StateLoc 23 (WYOMING)

Carrier/Loc 0082600=StateLoc 24 (IOWA)
Carrier/Loc 0083100=StateLoc 25 (ALASKA)
Carrier/Loc 0083200=StateLoc 26 (ARIZONA)
Carrier/Loc 0083300=StateLoc 27 (HAWAII)
Carrier/Loc 0083400=StateLoc 28 (NEVADA)
Carrier/Loc 0083500=StateLoc 29 (OREGON)
Carrier/Loc 0083600=StateLoc 30 (WASHINGTON STATE)
Carrier/Loc 0086500=StateLoc 31 (PENNSYLVANIA)
Carrier/Loc 0087000=StateLoc 32 (RHODE ISLAND)
Carrier/Loc 0088000=StateLoc 33 (SOUTH CAROLINA)
Carrier/Loc 0088300=StateLoc 34 (OHIO)
Carrier/Loc 0088400=StateLoc 35 (WEST VIRGINIA)
Carrier/Loc 0090000=StateLoc 36 (TEXAS)
Carrier/Loc 0090100=StateLoc 37 (MARYLAND)
Carrier/Loc 0090200=StateLoc 38 (DELAWARE)
Carrier/Loc 0090300=StateLoc 39 (DISTRICT OF COLUMBIA)
Carrier/Loc 0090400=StateLoc 40 (VIRGINIA)
Carrier/Loc 0091000=StateLoc 41 (UTAH)
Carrier/Loc 0095100=StateLoc 42 (WISCONSIN)
Carrier/Loc 0095200=StateLoc 43 (ILLINOIS)
Carrier/Loc 0095300=StateLoc 44 (MICHIGAN)
Carrier/Loc 0095400=StateLoc 45 (MINNESOTA)
Carrier/Loc 0097320=StateLoc 46 (PUERTO RICO)
Carrier/Loc 0513000=StateLoc 47 (IDAHO)
Carrier/Loc 0544000=StateLoc 48 (TENNESSEE)
Carrier/Loc 0553500=StateLoc 49 (NORTH CAROLINA)
Carrier/Loc 1433000=StateLoc 50 (NEW YORK GHI)
Carrier/Loc 3114000=StateLoc 51 (NORTHERN CALIFORNIA)
Carrier/Loc 3114200=StateLoc 52 (MAINE)
Carrier/Loc 3114300=StateLoc 53 (MASSACHUSETTS)
Carrier/Loc 3114400=StateLoc 54 (NEW HAMPSHIRE)
Carrier/Loc 3114500=StateLoc 55 (VERMONT)
Carrier/Loc 3114600=StateLoc 56 (SOUTHERN CALIFORNIA OCCIDENTAL)

50.5.1 – *Jurisdiction Of Referred Laboratory Services*

Regardless of whether the laboratory that bills Medicare is the referring or reference laboratory, the laboratory that does the billing may bill only the carrier that services the jurisdiction in which the billing laboratory is physically located. The location of the draw station, when a separate draw station is employed, never determines claims filing jurisdiction.

50.5.2 - Examples of Reference Laboratory Jurisdiction Rules

(Rev. 23, 10-31-03)

B3-3102

EXAMPLE 1

Scenario 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.

Jurisdiction:
The carrier in Oregon has jurisdiction.

EXAMPLE 2

Scenario 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 basic metabolic panel and a B12 and folate. The Philadelphia laboratory performs the complete blood count, but the basic metabolic panel is performed at the Millville laboratory, while the B12 and folate is performed at the Boston Laboratory.

Jurisdiction:
The Pennsylvania carrier may retain jurisdiction for processing the claim for all of the services. The local carrier servicing Boston and/or Millville may have jurisdiction for processing their claims if those laboratories bill for the services they perform, but the Philadelphia laboratory is barred from billing for the services that Boston and Millville submit for payment.

EXAMPLE 3

Scenario 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.

Jurisdiction:

The carrier processing claims for providers/suppliers located in Delaware may retain jurisdiction for processing the claim. If the laboratory in Boston chooses to bill for the service to the Massachusetts carrier, then the Wilmington laboratory may not bill for the service.