
CMS Manual System

Pub. 100-04 Medicare Claims Processing

Department of Health &
Human Services (DHHS)
Centers for Medicare &
Medicaid Services (CMS)

Transmittal 85

Date: FEBRUARY 6, 2004

CHANGE REQUEST 3090

I. SUMMARY OF CHANGES: Carrier standard systems would price the payment of referred services based upon the zip code of where the service was performed versus the current use of a reference use only PIN.

NEW/REVISED MATERIAL - EFFECTIVE DATE: July 1, 2004

***IMPLEMENTATION DATE: July 6, 2004**

Disclaimer for manual changes only: The revision date and transmittal number apply only to the red italicized material. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will only receive the new/revised information, and not the entire table of contents.

II. SCHEDULE OF CHANGES (R = REVISED, N = NEW, D = DELETED)

| R/N/D | CHAPTER/SECTION/SUBSECTION/TITLE |
|-------|--------------------------------------------------------------------------|
| R | 16/Table of Contents |
| R | 16/10.1/Definitions |
| R | 16/40.1/Laboratories Billing for Referred Tests |
| N | 16/40.1.1/Claims Information and Claims Forms and Formats |
| N | 16/40.1.1.1/Paper Claim Submission to Carriers |
| N | 16/40.1.1.2/Electronic Claim Submission to Carriers |
| R | 16/50.1/Referring Laboratories |
| R | 16/50.4/Reporting of Pricing Localities for Clinical Laboratory Services |
| R | 16/50.5.1/Jurisdiction of Referral Laboratory Services |
| R | 16/50.5.2/Examples of Reference Laboratory Jurisdiction Rules |

*III. FUNDING:

These instructions should be implemented within your current operating budget.

IV. ATTACHMENTS:

| | |
|---|---------------------------|
| X | Business Requirements |
| X | Manual Instruction |
| | Confidential Requirements |
| | One-Time Only |

*Medicare contractors only

Attachment - Business Requirements

| | | | |
|-------------|-----------------|------------------------|---------------------|
| Pub. 100-04 | Transmittal: 85 | Date: February 6, 2004 | Change Request 3090 |
|-------------|-----------------|------------------------|---------------------|

I. GENERAL INFORMATION

A. Background:

Full implementation of this change request (CR) will be implemented in the July 2004 release. This CR supercedes CR 2193.

Medicare recognizes that a clinical diagnostic laboratory may refer a specimen to another clinical diagnostic laboratory for testing. Generally, Medicare requires that the entity that furnishes the service, in this case the clinical diagnostic laboratory that performs the test, bill for the service. However, § 1833(h)(5)(A)(ii) of the Social Security Act permits, under certain conditions, a clinical diagnostic laboratory to bill for a clinical diagnostic laboratory fee schedule service that was performed by another clinical diagnostic laboratory. This Transmittal updates the claims processing rules for processing claims submitted by independent clinical diagnostic laboratories when the claim is for a service referred by one laboratory to another.

Medicare uses certain terms of art in the context of laboratory-to-laboratory referrals. Medicare defines a referred clinical diagnostic laboratory service/test as a service performed by one laboratory at the request of another laboratory. "Referring laboratory" is defined as the laboratory that refers a specimen to another laboratory for testing. "Reference laboratory" is defined as the laboratory that receives a specimen from another laboratory and that performs one or more tests on such specimen.

Medicare's payment policy for laboratory services is, generally, based on fee schedules and each carrier jurisdiction has its own fee schedule. Many carriers have been unable to process a claim for a referred clinical diagnostic laboratory test when the test was performed in another jurisdiction because they did not possess the fee schedule of that other jurisdiction. Moreover, carriers have not been required to adjudicate a claim for a referred service furnished in another jurisdiction unless it happened to have available the clinical laboratory fee schedule for such jurisdiction. Thus, some carriers paid for referred services performed outside of their jurisdiction and some did not.

Some referring laboratories electing to bill for a referred service performed in another jurisdiction have been unable to have the claim processed by the carrier in which they are enrolled. These laboratories have attempted to overcome the difficulty by enrolling as a reference laboratory with the carrier having jurisdiction where the test was performed. Some carriers have permitted such enrollments and issued a Provider

Identification Number (PIN) for the reference laboratory as a “reference-use-only” PIN. However, not every carrier has been willing to issue “reference-use-only” PINs.

These instructions resolve these issues by requiring that: 1) an independent clinical laboratory may bill only the carrier in which it is enrolled by reason of having a physical presence; 2) an independent clinical laboratory may not enroll with a carrier as a “reference-use-only” laboratory; 3) every carrier must adjudicate a claim for a referred service, regardless of where the service was performed, if the claim is submitted by a laboratory located in its jurisdiction; 4) every carrier must pay for a referred service on the basis of the fee schedule in effect in the jurisdiction where the test was performed; 5) every carrier must cancel all existing “reference-use-only” enrollments and “reference-use-only” PINs and refrain from making any further “reference-use-only” enrollments; 6) the referring laboratory must identify a referred service as such on the claim and identify the reference laboratory performing such test; and 7) both the referring laboratory and the reference laboratory must be enrolled in Medicare.

A. Policy: Although Medicare payment may generally be made to an independent clinical laboratory only for those tests that it performs, payment may also be made to a laboratory for a test that is on the clinical laboratory fee schedule that it has referred to another laboratory, provided the referring laboratory meets one of the following three conditions:

- It is located in, or is part of, a rural hospital;
- It is wholly-owned by the reference laboratory; or both it and the reference laboratory are wholly-owned subsidiaries of the same entity; or
- It refers no more than thirty (30) percent of the clinical laboratory tests annually to other laboratories, (not including referrals made under the wholly-owned proviso, above).

The Medicare allowed amount for a referred test is based on the fee schedule in effect where the test was performed. For services that are carrier priced, the reimbursement amount will be based upon the price developed by the carrier processing the claim.

The billing laboratory, whether it is the referring laboratory or the reference laboratory, must submit its claim to the carrier in which it is enrolled by reason of having a physical presence.

When the billing laboratory is the referring laboratory it must:

- Identify the referred service as such by use of modifier 90, and
- Identify the reference laboratory by specifying its CLIA number and address (i.e., the address where the test was actually performed).

General Requirements

- Disenroll out-of-jurisdiction laboratories that were previously enrolled for the purpose of billing referred services and cancel all “reference-use-only” PINs;
- Return as unprocessable claims submitted by out-of-jurisdiction laboratories;
- Process claims submitted for referred services from an independent clinical laboratory enrolled in its jurisdiction by reason of having a physical presence within its jurisdiction;
- Return as unprocessable a claim for a referred test (identified by the modifier 90) if the claim does not specify (for each item so identified) the address and CLIA number of the reference laboratory;
- Maintain the laboratory fee schedules for all carrier jurisdictions;
- Base the payment amount of a referred service on the fee schedule of the jurisdiction in which the test was performed (use the numerical locality code to identify the appropriate fee schedule; this data is available on the clinical diagnostic lab fee schedule) or, if such fee schedule does not have a price for the referred service, the carrier must base the payment amount on its own fee schedule amount or, if none, on a price it develops; and
- The general requirements are for dates of service July 1, 2004 or later.

Paper Claim Submission

Provider Information:

Suppliers that submit claims in the paper format (CMS-500 claim form) may not combine services that they performed themselves and any that they referred to another laboratory on the same CMS-1500 claim form. If a billing laboratory performs some testing and refers the remaining tests to another (reference) laboratory to perform, the laboratory must separate the services and submit two separate claims. If services are referred to more than one laboratory, a separate claim must be submitted for each reference laboratory, a separate claim must be submitted for each reference laboratory to which services were referred. Referral laboratory claims submitted to carriers are permitted only for independent clinical laboratories, specialty code 69. The line items submitted for referred lab test must contain a modifier 90. The performing laboratory’s name and address must be reported in item 32 on the CMS-1500 form to show where the service (test) was actually performed.

CLIA Number:

A paper claim for laboratory testing requires the presence of the CLIA number of the lab performing the testing in item 23 on the CMS-1500 billing form. A claim for laboratory testing must be submitted as follows:

- Paper Claim: the billing laboratory performs all laboratory testing.

The facility submits a single claim for CLIA-covered laboratory tests and reports the CLIA number of the billing laboratory that is performing the testing in item 23 on the CMS-1500 form.

- Paper Claim: Billing laboratory performs some laboratory testing; some testing is referred to another laboratory.

If a billing laboratory performs some testing and refers the remaining tests to another (reference) laboratory to perform, the facility must split the claim and submit two separate claims. Paper claims will be returned as unprocessable if billing providers combine clinical lab services performed themselves and any referred to another lab on the same CMS 1500 form. On each claim, the CLIA number of the laboratory that is actually performing the testing must be reported in item 23 on the CMS-1500 form. Referral laboratory claims are permitted only for independently billing clinical laboratories, specialty code 69.

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.

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.

Electronic Claim Submission

American National Standards Institute (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 clinical diagnostic laboratory will not have to submit separate claims for referred and performed services. The 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 ANSI 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 in the appropriate 837 Loop.

National Standard Format (NSF) Electronic Claims:

Suppliers that submit claims in the NSF format may not combine services that they performed themselves and any that they referred to another laboratory on the same NSF claim form. If a billing laboratory performs some testing and refers the remaining tests to another (reference) laboratory to perform, the laboratory must segment the services and submit two separate claims. If services are referred to more than one laboratory, a separate claim must be submitted for each reference laboratory to which services were referred. Referral laboratory claims submitted to carriers are permitted only for independent clinical laboratories, specialty code 69. The line items submitted for referred lab test must contain a modifier 90. CLIA number:

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

The electronic claim will require two submittals when billing for performed services and reference services. For the first submittal the CLIA number for the billing lab must be item 23 of the claim with the tests they performed. For the second claim, the CLIA number for the reference laboratory must be in item 23 of the claim where the tests were not performed by the billing lab. The presence of the '90' modifier at the line item identifies the referral tests. Referral laboratory claims are only permitted for independently billing clinical laboratories, specialty code 69.

NSF Claim: the billing laboratory performs all laboratory testing.

The CLIA number assigned to the billing laboratory shall be reported in:

FA0 – 34.0

NSF Claim: Billing laboratory performs some laboratory testing; some testing is referred to another laboratory.

The CLIA number assigned to the performing laboratory 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:

- EA0 Field 39 Facility/Lab Name
- EA1 Field 06 Facility/Lab ADDR1
- EA1 Field 07 Facility/Lab ADDR2
- EA1 Field 08 Facility/Lab City
- EA1 Field 09 Facility/Lab State
- EA1 Field 10 Facility/Lab Zip Code

C. Provider Education: This change request (CR) supercedes the requirements for CR 2193. Notify providers that effective July 1, 2004, submit claims for dates of services July 1, 2004 or later based upon the procedures outlined in this instruction.

Revise the information posted on your Web site for CR 2193 to state that CMS is not implementing the requirements on April 1, 2004. If a provider bulletin has been released for CR 2193, retract the article in your next scheduled bulletin. Carriers that have not released any information in a bulletin should not post an article on CR 2193 in their next regularly scheduled bulletin.

Carriers shall inform affected provider communities by posting either a summary or relevant portions of this instruction on their Web sites within 2 weeks of the issuance date of this instruction. In addition, this same information shall be published in your next regularly scheduled bulletin. If you have a listserv that targets the affected provider communities, you must use it to notify subscribers that information about Processing Claims for Referred Services for a Independent Clinical Laboratory is available on your Web site.

II. BUSINESS REQUIREMENTS

"Shall" denotes a mandatory requirement
"Should" denotes an optional requirement

| Requirement # | Requirements | Responsibility |
|----------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| 3090.1 | All carrier standard systems shall make all of the clinical laboratory fee schedules for the entire United States available to all of their carriers for the processing of diagnostic laboratory claims for dates of service July 1, 2004 and later. | Standard Systems |
| 3090.2 | All carrier standard systems shall process claims for clinical laboratory services based | Standard Systems |

| | | |
|---------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|
| | upon where the service is performed when the line item contains a modifier 90 for dates of service July 1, 2004 and later. | |
| 3090.3 | All carriers shall pay for claims for referred diagnostic laboratory services based upon the fee schedule amount for where the service is performed. | Standard Systems |
| 3090.4 | All carrier standard systems shall make the determination of the appropriate fee schedule amount for all of the line items based upon the zip code for claims with dates of service July 1, 2004 and later. | Standard Systems |
| 3090.5 | All carriers shall identify all independent clinical laboratories enrolled that do not have a physical presence in their jurisdiction and cancel the PIN. Notify the supplier of the action taken. | Carriers |
| 3090.6 | Carrier Standard Systems shall assign a distinct locality code for specialty 69 line items with a modifier 90 based upon the clinical laboratory fee schedule. This code can be found on the clinical laboratory fee schedule. | Standard Systems |
| 3090.7 | CWF shall bypass the locality code edit (74x1) for specialty type 69. | CWF |
| 3090.8 | Standard Systems shall price automated multi channel tests (AMCC) referred services separate from non-referred AMCC tests. | Standard Systems |
| 3090.9 | Carriers shall return as unprocessable claims that contain a modifier 90 on the line item but lacks the address or CLIA information. Use remittance remark advice M58. | Carriers |

II. SUPPORTING INFORMATION AND POSSIBLE DESIGN CONSIDERATIONS

A. Other Instructions: N/A

| X-Ref Requirement # | Instructions |
|---------------------|--------------|
| | |

B. Design Considerations: N/A

| X-Ref Requirement # | Recommendation for Medicare System Requirements |
|---------------------|-------------------------------------------------|
| | |

C. Interfaces: N/A

D. Contractor Financial Reporting /Workload Impact: N/A

E. Dependencies: N/A

F. Testing Considerations: N/A

IV. SCHEDULE, CONTACTS, AND FUNDING

| | |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------|
| <p>Effective Date: July 1, 2004</p> <p>Implementation Dates: July 6, 2004</p> <p>Pre-Implementation Contact(s): Joan Proctor-Young (410) 786-0949 Tracey Hemphill (410) 786-7169</p> <p>Post-Implementation Contact(s): Regional office</p> | <p>These instructions should be implemented within your current operating budget.</p> |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------|

Medicare Claims Processing Manual

Chapter 16 - Laboratory Services

Table of Contents

(Rev. 85, 02-06-04)

40.1.1 Claims Information and Claims Forms and Formats

40.1.1.1 Paper Claim Submission to Carriers

40.1.1.2 Electronic Claim Submission to Carriers

50.5.1 Jurisdiction of Referral Laboratory Services

10.1 - Definitions

(Rev. 85, 02-06-04)

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 to 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 Laboratory 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. 85, 02-06-04)

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 non-related 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 non-related laboratory. Only 23 percent of the tests were referred to non-related 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 and Formats

(Rev. 85, 02-06-04)

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

(Rev. 85, 02-06-04)

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). The line item services must be submitted with a modifier 90.

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.*

40.1.1.2 - Electronic Claim Submission to Carriers

(Rev. 85, 02-06-04)

Electronic Claim Submission

American National Standards Institute (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 appropriate 837 loop.

National Standard Format (NSF) Electronic Claims:

An independent clinical laboratory that submits claims in the NSF format) may not combine non-referred (i.e., self-performed) and referred services on the same NSF 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 NSF claim that contains both non-referred and referred tests is returned as unprocessable.

CLIA number:

An NSF claim for laboratory testing will require the presence of the performing 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 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:

EA0 Field 39 Facility/Lab Name
EA1 Field 06 Facility/Lab ADDR1
EA1 Field 07 Facility/Lab ADDR1
EA1 Field 08 Facility/Lab City
EA1 Field 09 Facility/Lab State
EA1 Field 10 Facility/Lab Zip Code

50.1 - Referring Laboratories

(Rev. 85, 02-06-04)

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. 85, 02-06-04)

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

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

INTERMEDIARY RECORD LAYOUT FOR DATA FILE CLINICAL LABORATORY FEE SCHEDULE

| <i>Data Element Name</i> | <i>Picture</i> | <i>Location</i> | <i>Comment</i> |
|--------------------------|----------------|-----------------|----------------|
| <i>HCPCS</i> | <i>X(05)</i> | <i>1-5</i> | |

| | | | |
|-------------------------|-----------------|--------------|---------------------------------|
| <i>Filler</i> | <i>X(04)</i> | <i>6-9</i> | |
| <i>60% Pricing Amt</i> | <i>9(05)V99</i> | <i>10-16</i> | |
| <i>62% Pricing Amt</i> | <i>9(05)V99</i> | <i>17-23</i> | |
| <i>Filler</i> | <i>X(07)</i> | <i>24-30</i> | |
| <i>Carrier Number</i> | <i>X(05)</i> | <i>31-35</i> | |
| <i>Carrier Locality</i> | <i>X(02)</i> | <i>36-37</i> | <i>00--Single State Carrier</i> |
| | | | <i>01--North Dakota</i> |
| | | | <i>02--South Dakota</i> |
| | | | <i>20--Puerto Rico</i> |
| <i>State Locality</i> | <i>X(02)</i> | <i>38-39</i> | <i>See Attached</i> |
| <i>FILLER</i> | <i>X(21)</i> | <i>40-60</i> | |

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 Referral Laboratory Services

(Rev. 85, 02-06-04)

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. 85, 02-06-04)

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.