CMS Manual System	Department of Health & Human Services (DHHS) Centers for Medicare & Medicaid Services (CMS)	
Pub. 100-20 One-Time Notification		
Transmittal 20	Date: NOVEMBER 7, 2003	
	CHANGE REQUEST 2959	

I. SUMMARY OF CHANGES: 2004 Annual for Clinical Laboratory Fee Schedule and Laboratory Services Subject to Reasonable Charge Payment Method.

NEW/REVISED MATERIAL - EFFECTIVE DATE: January 1, 2004 *IMPLEMENTATION DATE: January 5, 2004

II. CHANGES IN MANUAL INSTRUCTIONS: (R = REVISED, N = NEW, D = DELETED

R/N/D	CHAPTER/SECTION/SUBSECTION/TITLE
N/A	

III. FUNDING: *Medicare contractors only:

These instructions should be implemented within your current operating budget.

IV. ATTACHMENTS:

	Business Requirements
	Manual Instruction
	Confidential Requirements
X	One-Time Notification

One-Time Notification

Pub. 100-20 | Transmittal: 20 | Date: November 7, 2003 | Change Request 2959

SUBJECT: 2004 Annual Update for Clinical Laboratory Fee Schedule and Laboratory Services Subject to Reasonable Charge Payment

I. GENERAL INFORMATION

A. Background:

This One-Time Notification provides instructions for the calendar year 2004 clinical laboratory fee schedule, mapping for new codes for clinical laboratory tests and update for laboratory costs subject to the reasonable charge payment method.

B. Policy:

Update to Fees

In accordance with §1833(h)(2)(A)(i) of the Social Security Act (the Act), the annual update to the local clinical laboratory fees for 2004 is 2.6 percent. Section 1833(a)(1)(D) of the Act provides that payment for a clinical laboratory test is the lesser of the actual charge billed for the test, the local fee, or the national limitation amount (NLA). For a cervical or vaginal smear test (pap smear), §1833(h)(7) of the Act requires payment to be the lesser of the local fee or the NLA, but not less than a national minimum payment amount (described below). However, for a cervical or vaginal smear test (pap smear), payment may also not exceed the actual charge. The Part B deductible and coinsurance do not apply for services paid under the clinical laboratory fee schedule.

National Minimum Payment Amounts

For a cervical or vaginal smear test (pap smear), §1833(h)(7) of the Act requires payment to be the lesser of the local fee or the NLA, but not less than a national minimum payment amount. Also, payment may not exceed the actual charge. The 2004 national minimum payment amount is \$15.14 (\$14.76 plus 2.6 percent update for 2004). The affected codes for the national minimum payment amount are 88142, 88143, 88147, 88148, 88150, 88152, 88153, 88154, 88164, 88165, 88166, 88167, 88174, 88175, G0123, G0143, G0144, G0145, G0147, G0148, and P3000.

National Limitation Amounts (Maximum)

For tests for which NLAs were established before January 1, 2001, the NLA is 74 percent of the median of the local fees. For tests for which NLAs are first established on or after January 1, 2001, the NLA is 100 percent of the median of the local fees in accordance with §1833(h)(4)(B)(viii) of the Act.

Access to Data File

The 2004 clinical laboratory fee schedule data file should be retrieved electronically through CMS' mainframe telecommunications system. Carriers should retrieve the data file on or after November 5, 2003. Intermediaries should retrieve the data file on or after November 20, 2003.

Internet access to the 2004 clinical laboratory fee schedule data file should be available after November 20, 2003, at http://www.cms.hhs.gov/paymentsystems. Medicaid State agencies, the Indian Health Service, the United Mine Workers, Railroad Retirement Board, and other interested parties should use the Internet to retrieve the 2004 clinical laboratory fee schedule. It will be available in multiple formats: Excel, text, and comma delimited.

Data File Format

Attachment A depicts the record layout of the 2004 clinical laboratory fee schedule data file for carriers. Attachment B depicts the record layout of the 2004 clinical laboratory fee schedule data file for intermediaries. For each test code, if your system retains only the pricing amount, load the data from the field named '60% Pricing Amt'. For each test code, if your system has been developed to retain the local fee and the NLA, you may load the data from the fields named '60% Local Fee Amt' and '60% Natl Limit Amt' to determine payment. For test codes for cervical or vaginal smears (pap smears), you should load the data from the field named '60% Pricing Amt' which reflects the lower of the local fee or the NLA, but not less than the national minimum payment amount. Intermediaries should use the field '62% Pricing Amt' for payment to qualified laboratories of sole community hospitals.

Attachment C lists new and deleted codes that are included in the 2004 clinical laboratory fee schedule data file. The 3-month grace period for deleted codes begins January 1, 2004.

Public Comments

On July 28, 2003, CMS hosted a public meeting to solicit input on the payment relationship between valid 2003 codes and new 2004 Current Procedural Terminology (CPT) codes. The meeting announcement was published in the **Federal Register** on June 27, 2003, pages 38370-38371 and on the CMS Web site. Recommendations were received from many attendees, including individuals representing laboratories, manufacturers, and medical societies. CMS posted a summary of the meeting and the tentative payment determinations on its Web site at http://www.cms.hhs.gov/paymentsystems. Additional written comments from the public were accepted until September 27, 2003.

Comments after the release of the 2004 laboratory fee schedule can be submitted to the following address so that CMS may consider them for the development of the 2005 laboratory fee schedule. A comment should be in written format and include clinical, coding, and costing information. To make it possible for CMS and its contractors to meet a January 5, 2005 implementation date, comments must be submitted before August 1, 2004.

Centers for Medicare & Medicaid Services (CMS) Center for Medicare Management Division of Ambulatory Services Mailstop: C4-07-07 7500 Security Boulevard Baltimore, Maryland 21244-1850

Pricing Information

The 2004 laboratory fee schedule includes separately payable fees for certain specimen collection methods (codes G0001, P9612, and P9615). The fees have been established in accordance with §1833(h)(4)(B) of the Act.

Instructions on separately payable fees for traveling to perform a specimen collection for either a nursing home or homebound patient were issued in June 1999. There are two

codes: P9603 for a per mileage trip basis or code P9604 for a flat rate trip basis where the average round trip is generally less than 20 miles (or an average of 10 miles per leg of the trip). To bill either code requires documentation of the number of specimens performed per trip (for both Medicare and non-Medicare patients) to compute the Medicare prorated fee. Code P9604 requires the laboratory to determine the appropriateness of billing on an average round trip basis for all trips during a one-year time period. Thus, payment for travel under code P9604 is made to reasonably pay on average for a varying range of trip miles so that the laboratory should not also require payment with another basis (e.g. code P9603). The payment for codes P9603 and P9604 reflects personnel and transportation costs. For dates of service January 1, 2004 through December 31, 2004, the personnel payment is \$.46 per mile. For dates of service January 1, 2004 through December 31, 2004, the standard mileage rate for transportation costs is \$0.375. The 2004 payment for code P9603 is \$.835 and for code P9604 is \$8.35. The standard mileage rate can also be found at the Web site www.irs.gov.

The 2004 laboratory fee schedule also includes codes that have a 'QW' modifier to both identify codes and determine payment for tests performed by a laboratory registered with only a certificate of waiver under the Clinical Laboratory Improvement Amendments of 1988 (CLIA).

For 2004, the clinical laboratory fee schedule will continue to include code G0001 Routine venipuncture for collection of specimen(s) and laboratories should continue to bill code G0001 for Medicare payment of venous blood collection by venipuncture. CPT code 36415 for Collection of venous blood by venipuncture and code 36416 Collection of capillary blood specimen (e.g., finger, heel, ear stick) remain invalid for Medicare purposes.

Based on comments, the mappings have been revised for codes 80157, 83663, 83664, 87046, 87071, 87073, 87254, 87300, and 88400. Mappings have been established for 82274 and 82274QW. Mappings have also been established for new codes G0328 and G0328QW. Code G0328's long descriptor is *Colorectal cancer screening*; fecal-occult blood test, immunoassay, 1-3 simultaneous determinations. The short descriptor is Fecal blood screening immunoassay.

Complete Blood Count (CBC) Testing

A complete blood count consists of measuring a blood specimen for levels of hemoglobin, hematocrit, red blood cells, white blood cells, and platelets. Also, a differential white blood cell (WBC) count measures the percentages of different types of white blood cells. This hematology testing is commonly ordered by physicians to diagnose and treat a wide array of disorders such as liver, heart, and pulmonary disease, hemorrhage, dehydration, and infections.

CPT codes representing component tests of CBC testing (with differential WBC testing) include:

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85004 Blood count; automated differential WBC count
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⁸⁵⁰⁰⁷ Blood count; microscopic examination with manual differential WBC count

⁸⁵⁰⁰⁸ Blood count; microscopic examination without manual differential WBC count 85009 Blood count; manual differential WBC count, buffy count

⁸⁵⁰¹³ Blood count; spun hematocrit

⁸⁵⁰¹⁴ Blood count; hematocrit (Hct)

⁸⁵⁰¹⁸ Blood count; hemoglobin (Hgb)

⁸⁵⁰³² Blood count; manual cell count (erythrocyte, leukocyte, or platelet)

⁸⁵⁰⁴¹ Blood count; red blood cell (RBC), automated

⁸⁵⁰⁴⁸ Blood count; leukocyte (WBC), automated

⁸⁵⁰⁴⁹ Blood count; platelet, automated

CPT codes representing the bundled testing services include:

85025 Complete CBC, automated (Hgb, Hct, RBC, WBC, and platelet count) and automated WBC differential 85027 Complete CBC, automated (Hgb, Hct, RBC, WBC, and platelet count)

National Correct Coding Initiative (NCCI) edits have been established to promote correct coding and prevent inappropriate payments. For example, test codes 85027 and 85004 should not be billed along with code 85025 which represents the bundled testing service. Further information on the NCCI edits is available at http://www.cms.hhs.gov/physicians/cciedits/default.asp

Based on comments, codes G0306 and G0307 have been established to permit continued billing of common bundled CBC testing services without a platelet count.

G0306 Complete (CBC), automated (Hgb, Hct, RBC, WBC, without platelet count) and automated differential WBC count

G0307 Complete (CBC), automated (Hgb, Hct, RBC, WBC, without platelet count)

If additional CBC component test(s) are medically necessary, only the medically necessary components (e.g. hemoglobin (Hgb) or hematocrit (Hct)) should be ordered and performed. Billing modifiers can assist in reporting additional medically necessary CBC component test(s) or bundling testing service for the same patient on the same date of service, such as modifier -91 Repeat clinical laboratory test.

Organ or Disease Oriented Panel Codes

Similar to prior years, the 2004 pricing amounts for certain organ or disease panel codes and evocative/suppression test codes were derived by summing the lower of the fee schedule amount or the NLA for each individual test code included in the panel code. The national limitation amount field on the data file is zero-filled.

Mapping Information for New and Revised Codes

New code 84156 is priced at the same rate as code 84155.

New code 84157 is priced at the same rate as code 84155.

New code 85055 is priced at the same rate as code 86361.

New code 87269 is priced at the same rate as code 87272.

New code 87329 is priced at the same rate as code 87328.

New code 87660 is priced at the same rate as code 87470.

New code 89225 is priced at the same rate as deleted code 89355.

New code 89235 is priced at the same rate as deleted code 89365.

New code G0306 is priced at the same rate as code 85025.

New code G0307 is priced at the same rate as code 85027.

New code G0328 is priced at the same rate as code 86318.

New code G0328QW is priced at the same rate as code 86318.

Gap-fill Payments for New Laboratory Tests

In accordance with §531(b) of the Benefits Improvement and Protection Act of 2000 (BIPA), CMS solicits public comments on determining payment amounts for new laboratory tests. As described earlier, CMS hosts an annual public meeting to allow parties the opportunity to provide input to the payment determination process. The CMS employs one of two approaches to establishing payment amounts for new laboratory test codes, crosswalking and gap-filling. After considering public input regarding the new test codes, CMS determines which approach is most appropriate for each new test code. In determining gap-fill amounts, the sources of information carriers should examine, if available, include: charges for the test and routine discounts to charges; resources required to perform the test; payment amounts determined by other payers; and charges, payment amounts, and resources required for other tests that may be comparable or otherwise relevant. Carriers may consider other sources of information as appropriate, including clinical studies and information provided by clinicians practicing in the area, manufacturers, or other interested parties.

After determining a gap-fill amount, a carrier may consider if a least costly alternative (LCA) to a new test exists (see Pub. 100-08, PIM Chapter 13, §5.4). Joint Signature Memorandum RO-2256, issued August 29, 2003 states that the method of implementing a LCA is through the Local Medical Review Policy (LMRP) process. If a carrier determines LCA, the carrier may adopt the payment amount of the LCA test code as the gap-fill amount for the new test code. However in this case, the carrier must report two payment amounts, the gap-fill amount prior to determination of LCA and the payment amount that the carrier has determined to be LCA.

For 2004, there are no new test codes to be gap-filled.

<u>Laboratory Costs Subject to Reasonable Charge Payment in 2004</u>

For outpatients, the following codes are paid under a reasonable charge basis. In accordance with §42 CFR 405.502 – 405.508, the reasonable charge may not exceed the lowest of the actual charge or the customary or prevailing charge for the previous 12-month period ending June 30, updated by the inflation-indexed update. The inflation-indexed update is calculated using the change in the applicable Consumer Price Index for the 12-month period ending June 30 of each year as prescribed by §1842(b)(3) of the Act and §42 CFR 405.509(b)(1). The inflation-indexed update for year 2004 is 2.1 percent.

Manual instructions for determining the reasonable charge payment can be found in the Medicare Claims Processing Manual, Pub. 100-04, chapter 23, §80-80.8. If there is insufficient charge data for a code, the instructions permit considering charges for other similar services and price lists.

When these services are performed for independent dialysis facility patients, Medicare Claims Processing Manual, Pub. 100-04, chapter 8, §60.3 instructs the reasonable charge basis applies. However, when these services are performed for hospital based renal dialysis facility patients, payment is made on a reasonable cost basis.

Also, when these services are performed for hospital outpatients, payment is made under the hospital outpatient prospective payment system (OPPS).

Blood Products

P9010 P9011 P9012 P9016 P9017 P9019 P9020 P9021 P9022 P9023 P9031 P9032 P9033 P9034 P9035 P9036 P9037 P9038 P9039 P9040 P9044 P9050 P9051 P9052 P9053 P9054 P9055 P9056 P9057 P9058 P9059

Also, the following codes should be applied to the blood deductible as instructed Pub. 100-01, chapter 3, §20.5-20.54 (formerly MCM 2455): P9010, P9016, P9021, P9022, P9038, P9039, P9040, P9051, P9054, P9055, P9056, P9057, P9058

Note: Biologic products not paid on a cost or prospective payment basis are paid based on §1842(o) of the Act. The payment limits based on section 1842(o), including the payment limits for codes P9041 P9043 P9045 P9046 P9047 P9048, should be obtained from the Single Drug Pricer.

Transfusion Medicine

86850 86860 86870 86880 86885 86886 86890 86891 86900 86901 86903 86904 86905 86906 86920 86921 86922 86927 86930 86931 86932 86945 86950 86965 86970 86971 86972 86975 86976 86977 86978 86985 G0267

Reproductive Medicine Procedures

89250 89251 89253 89254 89255 89257 89258 89259 89260 89261 89264 89268 89272 89280 89281 89290 89291 89335 89342 89343 89344 89346 89352 89353 89354 89356

C. Provider Education: Intermediaries and carriers shall inform affected providers by posting either a summary or relevant portions of this document on their Web site within two weeks. Also, intermediaries and carriers shall publish this same information in their next regularly scheduled bulletin. If they have a listserv that targets affected providers, they shall use it to notify subscribers that information about 2004 Annual Update for Clinical Laboratory Fee Schedule and Laboratory Services Subject to Reasonable Charge Payment is available on their Web site.

II. BUSINESS REQUIREMENTS

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

Requirement #	Requirements	Responsibility
2959.1	Contractors shall retrieve the 2004 clinical laboratory fee schedule data file from the CMS mainframe which will be available for carriers on November 5, 2003 and for intermediaries on November 20, 2003.	FI/Carrier
2959.2	Contractors shall apply the 3-month grace period for deleted codes beginning January 1, 2004.	FI/Carrier
2959.3	Contractors shall determine the reasonable charge for the codes identified as paid under a reasonable charge basis. Determining customary and prevailing charges should use data from July 1, 2002 through June 30, 2003, updated by the inflation-indexed update for year 2004 of 2.1 percent. When these services are performed for hospital based renal dialysis facility patients, payment is made on a	FI/Carrier

	reasonable cost basis.	
2959.4	Contractors and CWF shall recognize codes G0328 and G0328QW for dates of service on or after January 1, 2004. Code G0328's long descriptor is <i>Colorectal cancer screening; fecal-occult blood test, immunoassay, 1-3 simultaneous determinations.</i> G0328QW is the same as code G0328 with the addition of the 'QW' for a laboratory registered with only a certificate of waiver under the Clinical Laboratory Improvement Amendments of 1988 (CLIA). These codes were not included in the 2004 HCPCS file but they are included in the 2004 clinical laboratory fee schedule data file identified in business requirement 2959.1. The lab certification number for these codes is 310 and the Type of Service is 5.	FI/Carrier/CWF

III. SUPPORTING INFORMATION & POSSIBLE DESIGN CONSIDERATIONS

A. Other Instructions:

X-Ref Requirement #	Instructions
2959.1	Attachments A, B and D

B. Design Considerations:

X-Ref Requirement #	Recommendation for Medicare System Requirements
N/A	

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

Effective Date: January 1, 2004	These instructions should be
Implementation Date: January 5, 2004	implemented within your current operating budget
Pre-Implementation Contact(s):	
Anita Greenberg agreenberg@cms.hhs.gov	
410-786-4601	
Post-Implementation Contact(s): Regional Office	

ATTACHMENT A

CARRIER RECORD LAYOUT FOR DATA FILE

2004 CLINICAL LABORATORY FEE SCHEDULE

DATA SET NAME: MU00.@BF12394.CLAB.CY04.V1105

Data Element Name	<u>Picture</u>	Location	Comment
HCPCS CODE	X(05)	1-5	
CARRIER NUMBER	X(05)	6-10	
LOCALITY	X(02)	11-12	00Single State Carrier 01North Dakota 02South Dakota 20Puerto 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	0No Gap-fill Required 1Carrier Gap-fill 2Special Instructions Apply
MODIFIER	X(02)	56-57	Where modifier is
shown,			QW denotes a CLIA
waived test.			
STATE LOCALITY	X(02)	58-59	Separate instructions will be issued for the use of this field. See
attachment E			for a description of values.
FILLER	X(01)	60-60	

ATTACHMENT B

INTERMEDIARY RECORD LAYOUT FOR DATA FILE 2004 CLINICAL LABORATORY FEE SCHEDULE

DATA SET NAME:MU00.@BF12394.CLAB.CY04.V1120.FI

Data Element Name	<u>Picture</u>	Location	Comment
HCPCS	X(05)	1-5	
FILLLER	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	
LOCALITY	X(02)	36-37	00Single State Carrier 01North Dakota 02South Dakota 20Puerto Rico
STATE LOCALITY will be	X(02)	38-39 See desc	Separate instructions issued for this field. Attachment E for riptions of the values.
FILLER	X(07)	40-60	

ATTACHMENT C

2004 CLINICAL LABORATORY FEE SCHEDULE

I. New Codes

II. Deleted Codes

P9056 P9057 P9058 P9059

III. Codes That Require Gap-Fill Amounts

For 2004, there are no new test codes to be gap-filled.

ATTACHMENT D

CARRIER LOCALITY/STATE LOCALITY VALUES

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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)
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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)