Commonwealth of Massachusetts
Executive Office of Health and Human Services
Office of Medicaid
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Boston, MA 02111
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MassHealth
Transmittal Letter LAB-35
March 2010

TO: Independent Clinical Laboratories Participating in MassHealth

FROM: Terence G. Dougherty, Medicaid Director

RE: *Independent Clinical Laboratory Manual* (Revised Provider Regulations)

This letter transmits revised and expanded program regulations for the *Independent Clinical Laboratory Manual*, which are effective April 1, 2010. These amendments pertain to standing order requests, information required for written requests for laboratory services, record requirements, conditions relating to authorized prescribers, and EPSDT services.

If you have any questions about the information in this transmittal letter, please contact MassHealth Customer Service at 1-800-841-2900, e-mail your inquiry to providersupport@mahealth.net, or fax your inquiry to 617-988-8974.

NEW MATERIAL

(The pages listed here contain new or revised language.)

Independent Clinical Laboratory Manual

Pages iv, vi, vii, and 4-1 through 4-8

OBSOLETE MATERIAL

(The pages listed here are no longer in effect.)

Independent Clinical Laboratory Manual

Pages iv and 4-1 through 4-8 — transmitted by Transmittal Letter LAB-30

Page vi — transmitted by Transmittal Letter LAB-34

Page vii — transmitted by Transmittal Letter LAB-24

4. Program Regulations

The regulations and instructions governing provider participation in MassHealth are published in the Provider Manual Series. MassHealth publishes a separate manual for each provider type.

Manuals in the series contain administrative regulations, billing regulations, program regulations, service codes, administrative and billing instructions, and general information. MassHealth regulations are incorporated into the Code of Massachusetts Regulations (CMR), a collection of regulations promulgated by state agencies within the Commonwealth and by the Secretary of State. MassHealth regulations are assigned Title 130 of the Code. The regulations governing provider participation in MassHealth are assigned Chapters 400 through 499 within Title 130. Pages that contain regulatory material have a CMR chapter number in the banner beneath the subchapter number and title.

Administrative regulations and billing regulations apply to all providers and are contained in 130 CMR Chapter 450.000. These regulations are reproduced as Subchapters 1, 2, and 3 in this and all other manuals.

Program regulations cover matters that apply specifically to the type of provider for which the manual was prepared. For independent clinical laboratories, those matters are covered in 130 CMR Chapter 401.000, reproduced as Subchapter 4 in the *Independent Clinical Laboratory Manual*.

Revisions and additions to the manual are made as needed by means of transmittal letters, which furnish instructions for substituting, adding, or removing pages. Some transmittal letters will be directed to all providers; others will be addressed to providers in specific provider types. In this way, a provider will receive all those transmittal letters that affect its manual, but no others.

The Provider Manual Series is intended for the convenience of providers. Neither this nor any other manual can or should contain every federal and state law and regulation that might affect a provider's participation in MassHealth. The provider manuals represent instead MassHealth’s effort to give each provider a single convenient source for the essential information providers need in their routine interaction with MassHealth and its members.

401.401: Introduction

130 CMR 401.000 contains regulations governing independent clinical laboratory services under MassHealth. All independent clinical laboratories participating in MassHealth must comply with regulations governing MassHealth, including, but not limited to 130 CMR 401.000 and 450.000.

401.402: Definitions

The following terms used in 130 CMR 401.000 have the meanings given in 130 CMR 401.402 unless the context clearly requires a different meaning. The reimbursability of services defined in 130 CMR 401.402 is not determined by these definitions, but by application of regulations elsewhere in 130 CMR 401.000 and 450.000.

Authorized Prescriber — any individual who is authorized under state law to prescribe drugs pursuant to M.G.L. c. 94C and also authorized to order the test under M.G.L. c. 111D

Bulk Purchase — a single purchase of the same laboratory services (one or more tests) to be uniformly and concurrently performed on a minimum of 40 specimens.

Hospital Laboratory — a clinical laboratory that is owned and operated by a hospital, licensed by the Massachusetts Department of Public Health, and an approved Medicare provider.

Clinical Laboratory — a laboratory that conducts microbiological, serological, chemical, hematological, biophysical, radiobioassay, cytological, immunohematological, immunological, pathological, or other examinations of materials derived from the human body, to provide information for the assessment of a medical condition or for the diagnosis, prevention, or treatment of any disease.

Independent Clinical Laboratory — a freestanding clinical laboratory that is not affiliated with a hospital.

Panel Test — any group of tests, whether performed manually, automatedly, or semiautomatedly, that is ordered for a specified member on a specified day and has at least one of the following characteristics:

(1) the group of tests is designated as a panel by the clinical laboratory performing the tests; or
(2) the group of tests is performed by the clinical laboratory at a usual and customary fee that is lower than the sum of that laboratory's usual and customary fees for the individual tests in that group.

Referring Laboratory — a clinical laboratory that forwards specimens to another clinical laboratory for specific tests that cannot be performed by the referring laboratory.

Standing Order — a request by an authorized prescriber for an independent clinical laboratory to repeat one of more tests over a specified period of time.

Subsidiary-Related Entity — a wholly owned subsidiary of a testing or referring laboratory, or both.

Testing Laboratory — a clinical laboratory that performs one or more tests on a specimen forwarded by a referring laboratory.

Usual and Customary Fee — the lowest fee in effect at the time of service, other than a fee offered for a bulk purchase, that is charged by an independent clinical laboratory for any laboratory service, including profile tests, specified in the fee schedule or by the laboratory.

401.403: Eligible Members

(A) (1) MassHealth Members. The MassHealth agency covers independent clinical laboratory services only when provided to eligible MassHealth members, subject to the restrictions and limitations described in MassHealth regulations. MassHealth regulations at 130 CMR 450.105 specifically state, for each MassHealth coverage type, which services are covered and which members are eligible to receive those services.
(2) Recipients of the Emergency Aid to the Elderly, Disabled and Children Program. For information on covered services for recipients of the Emergency Aid to the Elderly, Disabled and Children Program, see 130 CMR 450.106.

(B) For information on verifying member eligibility and coverage type, see 130 CMR 450.107.

401.404: Provider Eligibility

An independent clinical laboratory must be enrolled in MassHealth on the date of service in order to be eligible for payment.

(A) In-State Providers. To be eligible to enroll as a MassHealth provider, an independent clinical laboratory must be
(1) located and doing business in the Commonwealth of Massachusetts;
(2) certified as an independent clinical laboratory by CMS, based on the criteria set forth in the Clinical Laboratory Improvement Amendments (CLIA) of 1988; and
(3) licensed as a clinical laboratory by the Massachusetts Department of Public Health.

(B) Out-of-State Providers. A clinical laboratory that does not meet the requirements of 130 CMR 401.404(A)(1) and (3) may enroll in MassHealth only if the clinical laboratory is licensed as a clinical laboratory in its own state and meets the requirements of 130 CMR 401.404(A)(2), 401.405, and 450.109.

(C) Multiple Facilities. When two or more independent clinical laboratories have the same director or owner, whether or not the laboratories have different names, each laboratory must enroll separately with the MassHealth agency and have its own MassHealth provider number.

401.405: Laboratory Services Provided outside of Massachusetts

When provided out of state, independent clinical laboratory services are reimbursable only if

(A) the member is temporarily out of state and requires clinical laboratory services under the circumstances described in 130 CMR 450.109;

(B) the MassHealth agency determines that the independent clinical laboratory services required by the member are not available from any laboratory in Massachusetts; or

(C) the out-of-state independent clinical laboratory is a subsidiary-related entity of an in-state independent clinical laboratory that is enrolled in MassHealth.

(130 CMR 401.406 through 401.409 Reserved)

401.410: Covered Services

MassHealth covers independent clinical laboratory services that are medically necessary for the diagnosis, treatment, and prevention of disease, and for the maintenance of the health of MassHealth members, subject to all restrictions and limitations described in 130 CMR 401.000 and 450.000.

401.411: Noncovered Services and Payment Limitations

(A) The MassHealth agency does not pay separately for routine specimen collection and preparation for the purpose of clinical laboratory analysis (for example, venipunctures; urine, fecal, and sputum samples; Pap smears; cultures; and swabbing and scraping for removal of tissue). The cost for such services is included in the payment for conducting the test and analysis.

(B) The MassHealth agency does not pay for the following services:
(1) laboratory tests associated with male or female infertility;
(2) calculations (for example, red cell indices, A/G ratio, creatinine clearance), and ratios calculated as part of a profile;
(3) tests performed for experimental or clinical investigational purposes (e.g., to establish safety and effectiveness), or that are themselves experimental or clinically investigational;
(4) tests performed only for purposes of civil, criminal, administrative, or social service agency investigations, proceedings, or monitoring activities;
(5) tests performed for residential monitoring purposes;
(6) tests performed to establish paternity;
(7) post-mortem examinations;
(8) tests where the request is not in accordance with 130 CMR 401.416;
(9) tests that are not medically necessary as defined in 130 CMR 450.204; and
(10) any other tests or activities performed for any purpose other than those described in 130 CMR 401.410.

(C) The MassHealth agency does not pay an independent clinical laboratory for services that the laboratory is not certified by CMS to perform.

401.412: Early and Periodic Screening, Diagnosis and Treatment (EPSDT) Services

The MassHealth agency pays for all medically necessary laboratory services for EPSDT-eligible members in accordance with 130 CMR 450.140 et seq., without regard to service limitations described in 130 CMR 401.000, and with prior authorization.

(130 CMR 401.413 and 401.414 Reserved)

401.415: Specimen Referral

(A) If an independent clinical laboratory cannot perform a requested test, it may refer the specimen to another laboratory that can perform the test. The testing laboratory must be an independent clinical laboratory or a hospital laboratory enrolled in MassHealth.

(B) When providing the test results, the referring laboratory must inform the authorized prescriber of the name and address of the testing laboratory.

(C) The testing laboratory must inform the referring laboratory of each test result within one business day of completing each test.

(D) The referring laboratory may not bill the MassHealth agency for tests performed by the testing laboratory.

(E) Under no circumstances may both the referring and testing laboratories bill for the same procedure performed on the same specimen.

401.416: Request for Laboratory Services

(A) Request Requirements. The independent clinical laboratory may not bill for a service unless it has received a written request to perform that specific service from an authorized prescriber who is treating the member and will use the test for the purpose of diagnosis, treatment, or an otherwise medically necessary reason as defined in 130 CMR 450.204. Any independent clinical laboratory billing for a service must maintain such request in its records, and make such records available to the MassHealth agency and the Attorney General's Medicaid Fraud Division upon request. If the laboratory that billed for the service cannot produce the original request, the MassHealth agency may deny or recover payment for all services the laboratory provided based on that request.

(B) Standing Orders. An authorized prescriber may request an independent clinical laboratory to perform one or more tests on a single date, or issue a standing order for such tests. Standing order requests may not exceed 180 days in length with the exception of standing order requests for substance abuse testing, which may not exceed 30 days in length. Standing order requests are not permissible unless such repeated tests are medically necessary and required as part of the member's medical or drug treatment plan.

(C) Required Information. Requests for laboratory services must be written and include the following information:

(1) the date of the request;
(2) the name or any other means of identifying the member to be tested;
(3) the name and address of the authorized prescriber;
(4) the name of the specific laboratory tests to be performed;
(5) the frequency for performing each laboratory test (applicable to standing orders only);
(6) the duration and maximum number of times each laboratory test or tests are to be performed (applicable to standing orders only); and
(7) a statement by the authorized prescriber that such testing is required as part of the member's medical or drug treatment plan (applicable to standing orders only).

(D) Recordkeeping. If a laboratory refers a specimen to a testing laboratory, the referring laboratory must forward the original request to perform the service to the testing laboratory. The testing laboratory must maintain such request in its records in accordance with 130 CMR 401.416(A).

401.417: Recordkeeping Requirements

Both referring and testing laboratories must keep a record of each written request for laboratory services, each specimen, and each test result for at least six years from the date on which the results were reported to the authorized prescriber. If the testing laboratory is a subsidiary-related entity of the referring laboratory, such records may be maintained at one location, but must be made available to the MassHealth agency and the Attorney General's Medicaid Fraud Division upon request, in accordance with 130 CMR 450.205. If an independent clinical laboratory cannot produce the record to substantiate a MassHealth claim, the MassHealth agency may deny or recover payment for that claim. The laboratory record must contain the following information:

(A) the written request for laboratory services with all information required by 401.416;

(B) the identification number of the specimen;

(C) the name or any other means of identifying the person from whom the specimen was taken;

(D) the name of the authorized prescriber and, if applicable, the referring laboratory that submitted the specimen;

(E) the date on which the specimen was collected by the authorized prescriber or laboratory, the location of the collection, and the name of the collector;

(F) the date on which the specimen was received in the laboratory;

(G) the condition of unsatisfactory specimens when received (for example, broken, leaked, hemolyzed, or turbid);

(H) the specific tests performed;

(I) the date or dates on which each test was performed;

(J) the results of each test, the name and address of all persons to whom each test result is reported, and the date of reporting; and

(K) the name and address of the laboratory to which the specimen was referred, if applicable.

401.418: Maximum Allowable Fees

(A) The Division of Health Care Finance and Policy (DHCFP) determines the maximum allowable fees for independent clinical laboratory services. The maximum allowable payment for a service is the lowest of the following:

(1) the amount listed in the applicable DHCFP fee schedule;
(2) the independent clinical laboratory's usual and customary fee; or
(3) the amount that would be recognized under 42 U.S.C. § 13951(h) for tests performed for a person with Medicare Part B benefits.

(B) The maximum allowable payment is full compensation for the laboratory service and any related administrative or supervisory duties in connection with the service, regardless of where the service was provided.

(C) An independent clinical laboratory cannot bill for more than its usual and customary fee for a service.

401.419: Individual Consideration

(A) Some tests listed in Subchapter 6 of the *Independent Clinical Laboratory Manual* are designated "I.C.," an abbreviation for individual consideration. A fee has not been established for these services. Payment for an individual-consideration service is determined by the MassHealth agency's professional advisers, based on the laboratory's description of the test, which must be included with the claim.

(B) If a test is not listed in Subchapter 6 of the *Independent Clinical Laboratory Manual*, an independent clinical laboratory may submit a claim by using the appropriate "unlisted test" service code. Payment for an unlisted test is determined by individual consideration, based on the laboratory's description of the test, which must be included with the claim.

(C) The MassHealth agency considers the following factors when determining the appropriate payment for an individual-consideration service:

(1) the amount of time required to perform the service;
(2) the degree of skill required to perform the service;
(3) policies, procedures, and practices of other third-party payers;
(4) prevailing medical-laboratory ethics and accepted custom of the medical-laboratory community; and
(5) other standards and criteria as may be adopted by DHCFP.

401.420: Panel Tests

The MassHealth agency does not pay an independent clinical laboratory separately for a test included in a panel test when a panel test has been performed by that laboratory or requested by an authorized prescriber.

401.421: Quality Assurance and Provider Review

The MassHealth agency conducts reviews of providers and administers quality-control programs to ensure that MassHealth members are receiving high-quality medical services. An independent clinical laboratory must maintain its own quality-control program and successfully participate in one or more proficiency testing programs that cover all Medicare-certified specialties and subspecialties of the laboratory. The laboratory must make the results of the proficiency testing programs available to the MassHealth agency and the Attorney General's Medicaid Fraud Division upon request or during an on-site visit.

REGULATORY AUTHORITY

130 CMR 401.000: M.G.L. c. 118E, §§ 7 and 12.