Commonwealth of Massachusetts
Executive Office of Health and Human Services
Office of Medicaid
100 Hancock St.
Quincy, MA 02171
www.mass.gov/masshealth

MASSHEALTH
TRANSMITTAL LETTER LAB-38
December 2011

TO: Independent Clinical Laboratories Participating in MassHealth

FROM: Julian J. Harris, M.D., Medicaid Director

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

This letter transmits revisions to the definition of authorized prescribers for independent clinical laboratory providers (at 130 CMR 401.402) and also to the regulation governing requests for laboratory services (at 130 CMR 401.416). The authorized prescriber definition is revised to Department of Public Health (DPH) licensed substance abuse treatment programs to prescribe medically necessary drug screen services.

Such requests must be initiated in writing by a physician who is employed or contracted by the substance abuse treatment program, and whose written request fully complies with all requirements set forth in 130 CMR 401.416(A), (B), and (C), including the requirement that standing order requests for substance abuse testing not exceed 30 days in length. These regulation changes have been made pursuant to Section 63 of Chapter 288 of the Acts of 2010.

These changes are effective with dates of service on or after January 1, 2012.

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 4-1, 4-2, 4-5, and 4-6

OBSOLETE MATERIAL

(The pages listed here are no longer in effect.)

Independent Clinical Laboratory Manual

Pages 4-1, 4-2, 4-5, and 4-6 – transmitted by Transmittal Letter LAB-35

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 and for the sole purpose of ordering medically necessary drug screen services, Massachusetts Department of Public Health licensed substance abuse treatment programs only when such requests are initiated in writing by a physician who is employed or contracted by the substance abuse treatment program to make such requests and whose written request fully complies with all requirements set forth in 130 CMR 401.416(A) through (C).

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.

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.

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.

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 or 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 the Centers for Medicare & Medicaid Services (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.

401.415: 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 (if the authorized prescriber is a Massachusetts Department of Public Health licensed substance abuse treatment program for the sole purpose allowed pursuant to 130 CMR 401.402, the request must include the names and addresses of both the substance abuse treatment program and the physician initiating the request);
(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.