DATE: May 31, 2016

TO: Interested Parties

FROM: Stefanie Nadeau, Director, MaineCare Services

SUBJECT: Proposed Rule: Chapter 101, MaineCare Benefits Manual, Section 55, Chapter II, Laboratory Services

PUBLIC HEARING: June 28, 2016, 9:00 AM, Room 110, 19 Union Street, Augusta, ME 04330

COMMENT DEADLINE: Comments must be received by midnight July 8, 2016

This letter gives notice of a proposed rule: Chapter 101, MaineCare Benefits Manual, Section 55, Chapter II, Laboratory Services.

This rule is being proposed in order to limit and align urine drug testing to current industry standards. The Department proposes the following:

- Drug testing must be supported by documentation in the medical record.
- The frequency and choice of assay used should be based on an assessment of the individual member’s risk potential.
- Separate payment for testing of adulterants or specimen validity is not reimbursable.
- Confirmation testing is covered only to confirm an unexpected result.
- Urine drug testing is limited to two (2) specimens per rolling month. Additional test(s) may be requested with a Prior Authorization.
- Substance abuse treatment is to be measured by random testing rather than scheduled testing.
- Routine urine drug screening should focus on detecting specific drugs of concern.
- A presumptive test may be followed by a definitive test to specifically identify drugs or metabolites. Confirmation tests must be performed by a second method. A presumptive test to confirm a presumptive test is not reimbursable.
- Standing orders for presumptive testing must be signed and dated no more than sixty (60) days prior to the date of specimen collection. Standing orders for conformation and/or quantitative testing is prohibited.
- The Department clarifies what is considered not medically necessary.

The Department also proposes adding language for Prior Authorization to the Definitions.

Rules and related rulemaking documents may be reviewed at, or printed from, the MaineCare website at http://www.maine.gov/dhhs/oms/rules/index.shtml or for a fee, interested parties may request a paper copy of rules by calling (207) 624-4050 or Maine Relay number 711.

A concise summary of the proposed rule is provided in the Notice of Agency Rulemaking Proposal, which can be found at http://www.maine.gov/sos/cec/rules/notices.html. This notice also provides information regarding the rulemaking process. Please address all comments to the agency contact person identified in the Notice of Agency Rulemaking Proposal.
Notice of Agency Rule-making Proposal

AGENCY: Department of Health and Human Services, MaineCare Services

CHAPTER NUMBER AND TITLE: 10-144 C.M.R., Chapter 101, MaineCare Benefits Manual, Section 55, Chapter II, Laboratory Services

PROPOSED RULE NUMBER:

CONCISE SUMMARY: This rule is being proposed in order to limit and align urine drug testing to current industry standards. The Department proposes the following:

- Drug testing must be supported by documentation in the medical record.
- The frequency and choice of assay used should be based on an assessment of the individual member’s risk potential.
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- The Department clarifies what is considered not medically necessary.

The Department also proposes adding language for Prior Authorization to the Definitions.


STATUTORY AUTHORITY: 22 M.R.S. §§ 42, 3173

PUBLIC HEARING:

Date: June 28, 2016
Time: 9:00 AM
Location: Room 110, 19 Union Street, Augusta, ME 04330

The Department requests that any interested party requiring special arrangements to attend the hearing contact the agency person listed below before June 21, 2016.
DEADLINE FOR COMMENTS: Comments must be received by 11:59 PM on July 8, 2016.

AGENCY CONTACT PERSON: Cari Bernier, Comprehensive Health Planner II
Cari.Bernier@maine.gov

AGENCY NAME: MaineCare Services

ADDRESS: 242 State St.
11 State House Station
Augusta, Maine 04333-0011

TELEPHONE: 207-624-4031 FAX: (207) 287-1864
TTY: 711 (Deaf or Hard of Hearing)

IMPACT ON MUNICIPALITIES OR COUNTIES (if any): The Department anticipates that this rulemaking will not have any impact on municipalities or counties.
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55.01 **DEFINITIONS**

55.01-1 **Laboratory Services**

Laboratory Services ordered by or under the direction of a physician or a licensed practitioner of the healing arts within the scope of his or her practice as defined by state law; and provided by a laboratory that is in compliance with the pertinent sections of 22 M.R.S.A. §2011 et seq. (Maine Medical Laboratory Act) and the rules and regulations promulgated thereunder, meets the requirements for participation in Medicare and is in compliance with the rules implementing the Clinical Laboratory Improvement Amendments of 1988 (CLIA 88).

55.01-2 **Medical/Clinical Laboratory**

Any institution, building or place which provides through its ownership or operation an organization which employs methods and instruments for the examination of blood, tissues, secretions, and excretions of the human body or any function of the human body in order to diagnose disease, follow the course of disease, aid in the treatment of such disease, or detect drugs or toxic substances or which produces information used as a basis for health advice or which purports to offer such examinations unless otherwise provided by law.

55.01-3 **Physician's Office Laboratory**

A laboratory operated by a physician or group practice exclusively to provide Laboratory Services for its own patients that is in compliance with the pertinent Sections of 22 M.R.S.A. §2011 et seq. and the rules and regulations promulgated thereunder and meets the requirements for participation in Medicare and is in compliance with the rules implementing the Clinical Laboratory Improvement Amendments of 1988 (CLIA 88).

55.01-4 **Practitioner of the Healing Arts**

Physicians and all others registered or licensed in the healing arts, including, but not limited to, nurse practitioners, podiatrists, optometrists, chiropractors, physical therapists, occupational therapists, speech therapists, dentists, psychologists and physicians’ assistants.

55.01-5 **Group Practice Laboratory**

A laboratory established for the mutual use of physician or group practice owners, is considered an Independent Clinical Laboratory (See 55.01-3 and 55.01-5).
55.01 **DEFINITIONS** (cont.)

55.01-6 Independent Clinical Laboratories

An Independent Clinical Laboratory is one which is not under direct jurisdiction of a hospital or the patient's attending physician. For reimbursement under Title XIX, the independent laboratory must be certified as an Independent Clinical Laboratory in accordance with the Medicare conditions of participation and must be licensed under the provisions of 22 M.R.S.A. §2011 et seq. and the rules and regulations promulgated thereunder and be in compliance with the rules implementing the Clinical Laboratory Improvement Amendments (CLIA 88).

55.01-7 Prior Authorization

Prior Authorization is the process of obtaining prior approval from the Department as to the medical necessity and eligibility for certain MaineCare services before they are delivered, as set forth herein and in Chapter I, Section 1 of the MaineCare Benefits Manual (MBM).

55.02 **ELIGIBILITY FOR CARE**

Individuals must meet the eligibility criteria as set forth in the *MaineCare Eligibility Manual*. Some members may have restrictions on the type and amount of services they are eligible to receive. It is the responsibility of the provider to verify a member’s eligibility for MaineCare, as described in *MaineCare Benefits Manual*, Chapter I, Section I, prior to providing services.

Additional specific eligibility criteria are set forth for each service.

55.03 **DURATION OF CARE**

Each Title XIX recipient is eligible for as many covered services as are medically necessary. The Department reserves the right to request additional information to evaluate and determine medical necessity.

55.04 **COVERED SERVICES**

55.04-1 General Provisions

A covered service is a service for which payment can be made by the Department.

Laboratory Services which are medically necessary for diagnosis and control of a medical condition, are covered services. These services must be ordered by a
physician or other licensed practitioner of the healing arts authorized to order lab services within the scope of his or her license and be consistent with good medical practice.

55.04.2 Bundling or Grouping of Laboratory Tests

Panels are tests that are frequently done as a group (profile) on automated equipment. If a group of tests overlaps two or more panels, the panel that incorporates the greater number of tests to fulfill the code definition is reimbursable. The remaining tests are individually reimbursable. Additionally, the provider shall not “unbundle” and bill separately for tests included as part of a group (profile or panel) that pay at a lower rate. Use the Physicians’ Current Procedural Terminology (CPT) Manual Codes for the proper Automated, Multichannel Tests, and for the proper Organ or Disease Oriented Panels.

As noted in Section 55.07(B) Medicaid will pay no more than the lowest amount payable by Medicare. Therefore, in those cases where the Medicaid allowance for a procedure exceeds the Medicare allowance, the program will pay the lowest Medicare-allowed rate.

55.04.3 DRUG TESTING

A. Clinical decision making for all drug testing including urine drug screening and confirmation testing must be supported by documentation in the medical record.

B. Frequency and choice of assay used should be based on medical necessity and a complete clinical assessment of the individual member’s risk potential for abuse and diversion.

C. The Department will not make separate payment for the testing of adulterants or specimen validity. There are a number of multi-panel, CLIA waived urine drug test kits available which test for pH, specific gravity, and oxidants to determine if the specimen has been adulterated.

D. Confirmation testing is covered only to confirm an unexpected result and must be requested in writing by the ordering provider.

A-E. Urine drug testing is limited to two (2) specimens per rolling month. Additional test(s) may be requested with a Prior Authorization.
55.04.3 **DRUG TESTING** (cont.)

B-F. Substance abuse treatment is to be measured by random testing rather than scheduled testing.

G. Routine urine drug screening is a presumptative procedure that should focus on detecting the specific drug(s) of concern based on the member’s medical history and/or the prevalence of drugs, geographically.

H. A presumptive (screening) test may be followed by a definitive (confirmation) test, in order to specifically identify drugs or metabolites. Such tests should be based on the member’s presentation and history and only include what is needed for safe patient management. The definitive test(s) must be supported by documentation that specifies the rationale for each definitive test ordered. Drug confirmation testing must be performed by a second method. A presumptive test cannot be performed to confirm a presumptive test.

I. Standing orders written to the laboratory for presumptive testing must be signed and dated by the ordering provider no more than sixty (60) days prior to the date of specimen collection. Standing orders must contain the frequency of laboratory testing and be documented in the member’s record. Standing orders for confirmation and/or quantitative testing are prohibited.

J. The following are not medically necessary:

1. Tests performed by an in-house laboratory and independent laboratory for the same test on the same date of service.

2. Reflex testing by the lab, based on a standing order.

3. Testing for residential monitoring.

4. Specimen validity testing.

5. Urine drug testing ordered by third parties, such as schools, courts, or employers or requested by a provider for the sole purpose of meeting the requirements of a third party.
55.05 POLICIES AND PROCEDURES

55.05-1 Physician's Office Laboratory

Physicians in private practice will be reimbursed only for those Laboratory Services provided in his/her office by the physician or the office staff, using the office equipment and supplies.

When only Laboratory Services are provided, an office visit charge may not be made.

55.05-2 Referrals

For necessary Laboratory Services not done in the physician's office, the physician may make a written referral to:

A. The laboratory department of a hospital;

B. An Independent Laboratory.

The physician may not charge for making the referral.

The provider of the service is to charge the Department of Human Services directly and provide a written report of test results to the physician.

Prohibition on referrals. Except as provided in federal rule, a physician who has a financial relationship with an entity, or who has an immediate family member who has a financial relationship with the entity, may not make a referral to that entity for the furnishing of clinical Laboratory Services for which payment otherwise may be made under Medicaid.

55.05-3 Proficiency Testing

The provider of the Laboratory Service shall participate in an on-going program of proficiency testing as described in 22 M.R.S.A. §2025 and the rules and regulations promulgated thereunder and the rules implementing the CLIA 88. Failure to demonstrate satisfactory participation to the Department of Health and Human Services, Maine Center for Disease Control & Prevention, Health and Environmental Testing Laboratory shall result in the provider being ineligible for reimbursement by the Medicaid program for those Laboratory Services found not to be in compliance.
55.05 **POLICIES AND PROCEDURES** (cont.)

55.05-4 **Bulk Purchase Discounts**

Purchase discounts have been classified as cash, trade, or quantity discounts. Cash discounts are reductions granted for the settlement of debts before they are due. Trade discounts are reductions from list prices granted to a class of customers before a consideration of credit terms. Quantity discounts are reductions from list prices granted because of the size of the individual or aggregate purchase transactions. Whatever the classification of purchase discounts, like treatment in reducing the billable costs is required.

All purchase discounts are reductions in cost and must be reflected in the amount billed the Department by the provider for Laboratory Services performed by a third party. The Department will pay only the lower of either the price established for said service in the Medicaid fee schedule, or the price actually paid by the provider to the third party for the service. The Department reserves the right to audit the provider's fiscal records in order to verify the proper application of any purchase discounts to the reduction of billable costs.

55.05-5 **Requirements for Out-of-State Providers**

Out-of-state laboratories, while not subject to the Department's proficiency testing program, are required to be Medicare certified and licensed by the Health Care Financing Administration under the Clinical Laboratory Improvement Amendment of 1988.

55.05-6 **Program Integrity**

A. The Division of Audit, Program Integrity monitors the medical services provided and determines the appropriateness and necessity of the services.

B. The Department and its professional advisors regard the maintenance of adequate client records as essential for the delivery of quality care. In addition, providers should be aware that these records are key documents in conducting post payment reviews. In the absence of proper and complete client records, no payment will be made and payments previously made may be recovered in accordance with Chapter I, Sec. 1 of the MaineCare Benefits Manual.

C. The Department requires that client records and other pertinent information will be transferred, upon request and with the client's signed release of information, to other providers involved in the client's care.
55.05 **POLICIES AND PROCEDURES** (cont.)

D. Upon request, the provider will furnish to the Department, without additional charge, the clinical records, or copies thereof, corresponding to and substantiating services billed by that provider.

55.06 **CONFIDENTIALITY**

The disclosure of information regarding individuals participating in the Medicaid program is strictly limited to purposes directly connected with the administration of the Medicaid program. Providers shall maintain the confidentiality of information regarding these individuals in accordance with 42 CFR §431 et seq. and other applicable sections of state and federal law and regulation.

55.07 **REIMBURSEMENT**

The MaineCare rates are posted on the Maine HealthPAS Portal Provider Fee Schedule. Rates other than drug prices for new or changed codes (any CPT or HCPCS code) are determined based on the following lowest benchmark:

A. The fee for service rate is set at seventy percent (70%) of the 2009 CMS rate or seventy (70%) of the rate in the year CMS assigns a rate for that code. Where no other options are applicable, the Department researches other State Medicaid agencies that cover the relevant service/code. The Department then bases its rates on the average cost of the relevant services/codes from those other agencies.; or

B. The lowest amount allowed by Medicare Part B for Maine area “99” fee including the appropriate Medicare fee adjustments for place of service and modifiers; or

C. If CMS approves, the provider's usual and customary charge.

In accordance with Chapter I, Sec. 1 of the MaineCare Benefits Manual, it is the responsibility of the provider to seek payment from any other source that is available for payment of a rendered service prior to billing the Office of MaineCare.

55.08 **COPAYMENT**

55.08-1 **Copayment Amount**

A. A copayment will be charged to each Medicaid recipient receiving services. According to the following schedule, the amount of the copayment shall not exceed $1.00 per day for services provided,
55.08 **COPAYMENT** (cont.)

<table>
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<th>Copayment Amount</th>
<th>Medicaid Payment for Services</th>
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<td>$10.00 or less</td>
<td>$ .50</td>
<td></td>
</tr>
<tr>
<td>$10.01 - or more</td>
<td>$1.00</td>
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B. The recipient shall be responsible for copayments up to $10.00 per month whether the copayment has been paid or not. After the $10.00 cap has been reached, the recipient shall not be required to make additional copayments and the provider shall receive full Medicaid reimbursement for covered services.

C. No provider may deny services to a recipient for failure to pay a copayment. Providers must rely upon the recipient's representation that he or she does not have the cash available to pay the copayment. A recipient's inability to pay a copayment does not, however, relieve him/her of liability for a copayment.

D. Providers are responsible for documenting the amount of copayments charged to each recipient (regardless of whether the recipient has made payment) and shall disclose that amount to other providers, as necessary, to confirm previous copayments.

55.08-2 **Copayment Exemptions:** No copayment may be imposed with respect to the following services:

A. Family planning services and supplies;

B. Services furnished to individuals under twenty-one (21) years of age;

C. Services furnished to any individual who is an inpatient in a hospital, skilled nursing facility, nursing facility, Intermediate Care Facility for Individuals with Intellectual Disabilities (ICF-IID), or other medical institution, if that individual is required, as a condition of receiving services in that institution, to spend for costs of medical care all but a minimal amount of his or her income required for personal needs;

D. Services furnished to pregnant women, including services provided during the three months following the end of a pregnancy;
55.08 **COPAYMENT** (cont.)

E. Emergency services, i.e.: when failure to provide the service could reasonably be expected to:

1. place the recipient's health in serious jeopardy,
2. cause serious impairment to bodily functions, or
3. cause serious dysfunction of any bodily organ or part.

F. Services furnished to an individual of a Health Maintenance Organization in which he or she is enrolled.

G. Recipients in State custody.

H. Recipients living in a Boarding Home or Foster Home.

Medicaid recipients exempt from copayment requirements are identified by a "NO" in the copay column on the recipient's Medical Eligibility Card.

See Section 55.09 for billing instructions for copayment exemptions.

55.09 **BILLING INSTRUCTIONS**

A. Billing must be accomplished in accordance with the Department's "Instructions for Completion CMS-1500 (02-12)."

B. All services provided on the same day must be submitted on the same claim form for Medicaid reimbursement.