Department of Health and Human Services
Maine People Living Safe, Healthy and Productive Lives

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Mary C. Mayhew, Commissioner
Department of Health and Human Services
11 State House Station • 221 State Street
Augusta, ME 04333

In the Matter of: Arnold Memorial Medical Center Provider ID No. 1205903820

ADMINISTRATIVE HEARING RECOMMENDED DECISION

An administrative hearing in the above-captioned matter was held on September 20, 2016, before Hearing Officer Richard W. Thackeray, Jr., at Augusta, Maine. The Hearing Officer's jurisdiction was conferred by special appointment from the Commissioner of the Maine Department of Health and Human Services. The hearing record was left open through October 21, 2016, to allow submission of written closing arguments.

Pursuant to an Order of Reference dated February 25, 2016, the issue presented *de novo* for hearing were whether the Maine Department of Health and Human Services ["Department"] was "correct when it determined for the review period from 1/1/2011 through 9/17/2012, Arnold Memorial Medical Center owes the department $970,315.55 pursuant to its Final Informal Review Decision dated November 23, 2015?" Ex. D-1.

APPEARING ON BEHALF OF THE APPELLANT

- Charles F. Dingman, Esq., PRETI FLAHERTY BELIVEAU & PACHIOS, LLP
- Michael S. Stewart, Esq., PRETI FLAHERTY BELIVEAU & PACHIOS, LLP
- Steven I. Weisberger, D.O., Medical Director, Arnold Memorial Medical Center
- Margaret Fortin, Senior Manager, BAKER NEWMAN & NOYES
- Eva Smith, Director of Billing, Arnold Memorial Medical Center
- Laurie Charbonneau, Administrator, Arnold Memorial Medical Center
- Sharon Trapp, Clinical Laboratory Supervisor, Arnold Memorial Medical Center

APPEARING ON BEHALF OF THE DEPARTMENT

- Thomas C. Bradley, AAG, MAINE OFFICE OF THE ATTORNEY GENERAL
- Eva Stewart, Comprehensive Health Planner II, Program Integrity, Division of Audit, Augusta

ITEMS INTRODUCED INTO EVIDENCE

Hearing Officer Exhibits

HO-1: "Reschedule Notice," dated May 17, 2016

HO-2: "Notice of Administrative Hearing," dated March 1, 2016

Department Exhibits

D-1: "Order of Reference," dated February 25, 2016

D-2: "Fair Hearing Report Form," dated February 22, 2016

D-3: "Notice of Violation," dated June 5, 2015; Billing Claims Spreadsheet (unredacted)

D-3a: "Billing Claims Spreadsheet" (redacted)

D-4: "Request for Informal Review," dated August 4, 2015

D-5: "Final Informal Review Decision," dated November 23, 2015

D-6: "Appeal and Request for Hearing," dated January 22, 2016

D-7: "MaineCare/Medicaid Provider Agreement," dated February 3, 2010

D-8: "Provider Enrollment Attestation Confirmation," dated December 16, 2009

D-9: "Final Rule," Office of MaineCare Services, effective date February 13, 2011

D-10: "Final Rule," Office of MaineCare Services, effective date January 13, 2010

D-11: "Final Rule," Office of MaineCare Services, effective date November 24, 2010

D-12: "Final Rule," Office of MaineCare Services, effective date November 29, 2010

D-13: "Types of CLIA Certificates," Centers for Medicare and Medicaid Services

D-14: "Clinical Laboratory Improvement Amendments (CLIA) and Medicare Laboratory Services," Centers for Medicare and Medicaid Services, dated August 2015

D-15: "CLIA Categorizations," Food and Drug Administration, dated April 13, 2016

D-16: "CLIA Laboratory Demographic Information Report," Arnold Memorial Medical Center

D-17: "Statement of Deficiencies/Compliance," Centers for Medicare and Medicaid Services, dated April 15, 2011

D-18: "Statement of Deficiencies/Compliance," Centers for Medicare and Medicaid Services, dated March 8, 2013

D-19: "Acon Drug Testing," DrugTesting-Kits.com, *available at* http://www.drugtesting-kits.com/Acon_Drug_Test_Cards_Cups.htm (visited on April 14, 2016)

D-20: "Acon 6 Panel Drug Testing Cassette," DrugTesting-Kits.com, *available at* http://www.drugtesting-kits.com/us/drugkits/cf.inventory.php?action=showinvdetail&invid... (visited on August 23, 2016)[1]

[1] The Hearing Officer takes official notice that the full URL address for the web page referenced in Exhibit D-20 is http://www.drugtesting-kits.com/us/drugkits/cf.inventory.php?action=showinvdetail&invid=495 (last visited on Jan. 10, 2017).

D-21: "Acon® One Step Drug Screen Test Card," CLIAwaved, Inc. (rev. 1.03.11)

D-22: "HCPCS Level II" (excerpt), Ingenix/American Medical Assn. (2011 Edition)

D-23: "HCPCS Level II" (excerpt), Ingenix/American Medical Assn. (2012 Edition)

D-24: "Billing Claims Spreadsheet," [redacted], February 22, 2011 to May 23, 2011 (unredacted)

D-24a: "Billing Claims Spreadsheet," [redacted], February 22, 2011 to May 23, 2011 (redacted)

D-25: "Billing Claims Spreadsheet," multiple members, January 3, 2011 to September 20, 2012 (unredacted)

D-25a: "Billing Claims Spreadsheet," multiple members, January 3, 2011 to September 20, 2012 (redacted)

D-26: "Excerpt from 2011 Clinical Diagnostic Laboratory Fee Schedule"

D-27: "Instruction Sheet – multi-CLIN ™ Drug Screen Test Device"

D-28: "Instruction Sheet – PregCheck+ ™ One-Step Early Pregnancy Test"

D-29: "Written Closing Argument," dated October 21, 2016

Appellant Exhibits

A-1: "Email Chain," Evan Stewart and Brenda L. Haney, dated July 23, 2013 to July 25, 2013

A-2: "Provider Listserve Post Re Urine Drug Test (UDT) Coding," dated August 12, 2013

A-3: "Email," Charles F. Dingman, Esq. to Beth Ketch, dated January 7, 2014

A-4: "Sample Billing Documents" (redacted), dated January 3, 2011

A-5: "Sample Billing Documents" (redacted)

A-6: "Program Memo: Change in FQHC and RHC Payment Rates," Health Care Financ. Admin., HCFA-Pub. 60A, January 2000

A-7: "Verification of Certification," Steven I. Weisberger, D.O., expires December 21, 2016

A-8: "Patient Rules for Suboxone Program," Arnold Memorial Medical Center

A-9: "Medication Agreement," Arnold Memorial Medical Center

A-10: "Package Insert – One Step Multi-Drug Multi-Line Screen Test Device," dated September 8, 2006

A-11: "Package Insert – One Step Buprenorphine Test Device," dated September 8, 2006

A-12: "Notice of Provider Enrollment" dated February 3, 2010

A-13: "MaineCare Fee Schedule" (excerpts), dated September 20, 2012

A-14: "MaineCare Fee Schedule" (excerpts), dated May 15, 2016

A-15: "Written Closing Argument," dated October 21, 2016

STANDARD OF REVIEW

The hearing officer reviews a Departmental claim for recoupment against an approved MaineCare services provider *de novo*. DHHS Administrative Hearing Regulations, 10-144 C.M.R. Ch. 1, § VII (C)(1); Provider Appeals, MaineCare Benefits Manual, 10-144 C.M.R. Ch. 101, sub-Ch. I, § 1.21-1 (A). The Department bears the burden to persuade the Hearing Officer that, based on a preponderance of the evidence, it was correct in establishing a claim for repayment or recoupment against an approved provider of MaineCare services. 10-144 C.M.R. Ch. 1, § VII (B)(1), (2).

LEGAL FRAMEWORK

The Department administers the MaineCare program, which is designed to provide "medical or remedial care and services for medically indigent persons," pursuant to federal Medicaid law. 22 M.R.S. § 3173. *See also* 42 U.S.C. §§ 1396a, *et seq.* To effectuate this, the Department is authorized to "enter into contracts with health care servicing entities for the provision, financing, management and oversight of the delivery of health care services in order to carry out these programs." *Id.* Enrolled providers are authorized to bill the Department for MaineCare-covered services pursuant to the terms of its Provider Agreement, Departmental regulations, and federal Medicaid law. "Provider Participation," MaineCare Benefits Manual, 10-144 C.M.R. Ch. 101, sub-Ch. I, § 1.03 (eff. Jan. 11, 2010). *See also* 42 C.F.R. § 431.107 (b) (state Medicaid payments only allowable pursuant to a provider agreement reflecting certain documentation requirements); 42 U.S.C. § 1396a (a)(27). Enrolled providers also "must … [c]omply with requirements of applicable Federal and State law, and with the provisions of [the MaineCare Benefits] Manual." 10-144 C.M.R. Ch. 101, sub-Ch. I, § 1.03-3 (S) (eff. Jan. 11, 2010). Enrolled providers are also required to maintain records sufficient to "fully and accurately document the nature, scope and details of the health care and/or related services or products provided to each individual MaineCare member." 10-144 C.M.R. Ch. 101, sub-Ch. I, § 1.03-3 (M) (eff. Jan. 11, 2010). "The Division of Audit or duly Authorized Agents appointed by the Department have the authority to monitor payments to any MaineCare provider by an audit or post-payment review." 10-144 C.M.R. Ch. 101, sub-Ch. I, § 1.16. Pursuant to federal law, the Department is also authorized to "safeguard against excessive payments, unnecessary or inappropriate utilization of care and services, and assessing the quality of such services available under MaineCare." 10-144 C.M.R. Ch. 101, sub-Ch. I, § 1.17. *See also* 10-144 C.M.R. Ch. 101, sub-Ch. I, § 1.18; 22 M.R.S. § 42 (7); 42 U.S.C. § 1396a (a)(27); 42 C.F.R. § 431.960. This includes the imposition of "sanctions and recoup(ment of) identified overpayments against a provider, individual, or entity," for any of 25 specific reasons, including:

- Breaching the terms of the MaineCare Provider Agreement, and/or the Requirements of Section 1.03-3 for provider participation.
- Failure to repay or make arrangements to repay overpayments or payments made in error.

MaineCare Benefits Manual, 10-144 C.M.R. Ch. 101, sub-Ch. I, § 1.19-1 (G), (U).

To investigate and establish a Section 1.19 sanction, the Department may employ any of eight types of "surveillance and referral activities," including "a post-payment review that may consist of member utilization profiles, provider services profiles, claims, all pertinent professional and financial records, and information received from other sources." 10-144 C.M.R. Ch. 101, sub-Ch. I, § 1.18 (D). After such review, the "Department may impose sanctions and/or recoup identified overpayments against a provider, individual, or entity for any" of 25 reasons, including "[f]ailure to repay or make arrangements to repay overpayments or payments made in error." 10-144 C.M.R. Ch. 101, sub-I, § 1.19-1 (U). Departmental remedies include "[w]ithholding or offset of future payments toward recoupment of prior MaineCare reimbursements." 10-144 C.M.R. Ch. 101, sub-I, § 1.19-2 (C).

If the review produces evidence that "a provider may have submitted bills and/or has been practicing in a manner inconsistent with program requirements, and/or may have received payment for which he or she may not be properly entitled, the Department shall notify the provider of the discrepancies noted." 10-144 C.M.R. Ch. 101, sub-Ch. I, § 1.19-4. The notice "shall set forth:

A. The nature of the discrepancies or violations;
B. The dollar value of such discrepancies or violations;
C. The method of computing such dollar value may be from:
    1. extrapolation from a systematic random sampling of records,
    2. a calculation from a selective sample of records, or
    3. a total review of all records.
D. Any further actions to be taken or sanctions to be imposed by the Department; and
E. Any actions required of the provider, and the right to request an informal review and administrative hearing, as set forth in Section 1.21. An adverse decision may be appealed pursuant to the procedures outlined in Section 1.21 of this Chapter. A request for review or proceedings there under, does not stay the sanction imposed by the Department.
F. Any sanctions, including outstanding monetary sanctions, will be a factor in determining whether an individual or entity will be considered for reinstatement as a participant in the MaineCare Program. Any request for reinstatement will be reviewed in relation to any decisions or actions made by the United States Department of Health and Human Services, to past actions in MaineCare and to other relevant factors such as professional sanctions.

Id.

RECOMMENDED FINDINGS OF FACT

1. In accordance with agency rules, the Arnold Memorial Medical Center ["Arnold"] was properly notified of the time, date, and location of the immediate proceeding. Ex. HO-1; Ex. HO-2.

2. Arnold is a Rural Health Clinic ["RHC"], located in Jonesport, Maine, providing a range of medical services that has included urine drug screening tests related to its provision of substance abuse treatment services. Ex. D-4.

3. Effective February 3, 2010, Arnold was enrolled as an approved provider under Maine's Medicaid program ["MaineCare"] pursuant to a "Medicaid/Maine Health Program Provider/Supplier Agreement" that it entered with the Department. Ex. D-7; Ex. A-12.

4. On an unspecified date prior to June 5, 2015, Departmental comprehensive health planner Eva Stewart undertook a review of Arnold's billing claims submitted between January 1, 2011 and September 17, 2012. Ex. D-3.

5. On June 5, 2015, the Department issued a Notice of Violation against Arnold alleging *inter alia* that Arnold was overpaid $970,315.55 during the period of January 1, 2011 to September 17, 2012. The Notice of Violation more specifically alleged the following:

> The claims data shows that AMMC billed and was paid for Urine Drug Testing Codes submitted on a HCFA as well as the encounter code (T1015) on a UB claim form. The correct billing for services would have been for codes T1015 and G0434 to be billed on one UB claim form. Submitting for Urine Drug Testing Codes on a HCFA resulted in an overpayment.

Ex. D-3.

6. On August 4, 2015, Arnold timely requested an informal review of the Department's June 5, 2015 Notice of Violation, specifically disputing the Department's central findings and arguing that:

- The identified drug screening tests were not within the scope of otherwise billed "Rural Health Clinic Core Services";
- Claims using "QW" code 80101 were correctly coded at the time the claims were submitted;

Ex. D-4.

7. On November 23, 2015, the Department issued a "Final Informal Review Decision," upholding the recoupment amount of $970,315.55 identified in the June 5, 2015 "Notice of Violation," and affirming the central finding that Arnold incorrectly billed for urine drug screening tests throughout the review period. Specifically, the Final Informal Review Decision reflected:

- The subject tests, i.e. "lateral flow chromatographic immunoassay testing" screens were "CLIA-waived," and therefore, "low complexity" or "simple"/"basic";
- The subject tests utilize cassettes costing $10.00 per pair, but were claimed with codes requesting payment "of over $200 per specimen regardless of the minimum cost and complexity of the testing";
- Correct coding for the subject tests was the general Rural Health Clinic ["RHC"] encounter rate of "T1015," with HCPCS Code G0434 for low-complexity urine drug screening.

Ex. D-5.

8. On January 22, 2016, Arnold timely requested an administrative hearing. Ex. D-6.

9. For the period of January 1, 2011 to September 17, 2012, industry standard for Medicaid RHC provider billing using the Healthcare Common Procedure Coding System ["HCPCS"] assigned Code G0434 to be "used to report simple testing methods, such as dipsticks, cups, cassettes, and cards, that give visual results." This included "any other type of drug screening test defined as CLIA waved (sic) test or a moderate complexity test, other than chromatographic." Industry standard also provided that a single unit of Code G0434 should be "reported per patient encounter regardless of the number of drug classes tested." Ex. D-23.

10. For the period of January 1, 2011 to September 17, 2012, industry standard for Medicaid RHC provider billing using the Healthcare Common Procedure Coding System ["HCPCS"] assigned Code G0431 for use "where a more complex instrumented device is required to perform some or all of the screening tests for the patient," and specifically for tests defined by CLIA as "high complexity" and which use "instrumented systems." Ex. D-23.

11. For the period of January 1, 2011 to September 17, 2012, industry standard for Medicaid RHC provider billing using the Healthcare Common Procedure Coding System ["HCPCS"] assigned code modifier "QW" for all tests that were CLIA-waived. Ex. D-22.

12. For the period of January 1, 2011 to September 17, 2012, Departmental regulations required Medicaid RHC providers to use code T1015 when billing for "core services" provided during all discreet patient visits to an RHC, and to co-list other appropriate procedure codes (CPT and HCPCS) reflecting procedures performed during the same patient RHC visit. Ex. D-11; Ex. D-12; Test. of Eva Stewart; Test. of Margert Fortin.

13. For the period of January 1, 2011 to September 17, 2012, the Department required use of the UB 04 claims form by Medicaid RHC providers when submitting claims for "core services" via code T1015 and co-listed procedure codes. Ex. D-11; Ex. D-12; Test. of Eva Stewart; Test. of Margaret Fortin.

14. From November 29, 2010 to August 12, 2013, the Department utilized a preferred coding process for high-complexity drug screening tests that required the use of HCPCS code G0431, but retained CPT code 80101 as an available, valid billing code for MaineCare RHC providers seeking reimbursement for high-complexity laboratory tests. Test. of Eva Stewart; Test. of Margaret Fortin.

15. On August 12, 2013, the Department provided informal notice by email to MaineCare providers subscribing to its provider list-serve identifying a series of billing codes for urine drug testing had been eliminated and applying retroactive effective dates. Among these was CPT code 80101, which included the notation: "end dated effective 12/31/2009 and will deny reimbursement." Ex. A-2; Test. of Eva Stewart; Test. of Margaret Fortin.

16. The Department did not provide any notice to RHC providers from November 29, 2010 to August 11, 2013, that CPT code 80101 was invalid or should otherwise not be used to submit claims for high-complexity laboratory tests. Test. of Eva Stewart.

17. For the period of January 1, 2011 to September 17, 2012, the correct billing process for an RHC seeking MaineCare reimbursement for a low-complexity, CLIA-waived urine drug screening test was to submit a single UB 04 claim form, and specifically list codes T1015 and G0434-QW. Ex. D-11; Ex. D-12; Test. of Eva Stewart; Test. of Margaret Fortin.

18. For the period of January 1, 2011 to September 17, 2012, it was Arnold's routine practice to bill MaineCare for 11 units-of-service when providing a single plastic cassette-style, lateral flow chromatographic immunoassay to MaineCare eligible patients, where such procedure screened a single urine sample for the presence of any of 11 drugs or drug metabolites, and to do so by submitted separate claims for a single drug screen coded with CPT code 80101 in parallel with claims coded with HCPCs G0434-QW on separate claim forms. A representative claim of this claim type identified a billed amount of $250.14 ($22.74 per unit x 11 units) for a single drug screening immunoassay performed. Ex. D-26; Test. of Eva Stewart; Test. of Margaret Fortin.

19. For the period of January 1, 2011 to September 17, 2012, it was Arnold's routine practice to bill Medicare for one unit-of-service when providing a single plastic cassette-style, lateral flow chromatographic immunoassay to MaineCare/Medicare "dual eligible" patients, where such procedure screened a single urine sample for the presence of any of 11 drugs or drug metabolites, and to do so by submitting a single claim form including HCPCs code G0434. Ex. D-3; Ex. D-26; Test. of Eva Stewart; Test. of Margaret Fortin.

20. The urine drug screening tests performed by Arnold during the review period of January 1, 2011 to September 17, 2012 were Acon-brand, lateral flow chromatographic immunoassays used to detect evidence of multiple drugs and drug metabolites in urine, and which are comprised of plastic cassettes featuring multiple test wells and corresponding negative/positive "control regions." Each single cassette could screen a single patient for as many as 11 drugs or drug metabolites from a single urine sample. These tests could be performed without any other instruments. Ex. D-17; Ex. D-18; Ex. D-21; Ex. D-27; Ex. A-10.

21. The lateral flow chromatographic immunoassay urine drug screening tests performed by Arnold during the review period of January 1, 2011 to September 17, 2012, which utilized plastic cassettes with multiple test wells and corresponding negative/positive "control regions," and which screened for as many as 11 drugs or drug metabolites from a single urine sample without any other instruments, were essential to its immediate diagnosis and treatment of substance addiction in its patients. Ex. D-17; Ex. D-18; Ex. D-21; Ex. D-27; Ex. A-10.

22. The lateral flow chromatographic immunoassay urine drug screening tests performed by Arnold during the review period of January 1, 2011 to September 17, 2012, which utilized plastic cassettes with

multiple test wells and corresponding negative/positive "control regions," and which screened for as many as 11 drugs or drug metabolites from a single urine sample without any other instruments, were low-complexity, CLIA-waived tests. Ex. D-17; Ex. D-18; Ex. D-21; Ex. D-27; Ex. A-10.

RECOMMENDED DECISION

The Department was **correct** when it determined, for the review period of January 1, 2011 to September 17, 2012, that Arnold Memorial Medical Center was overpaid $970,315.55, pursuant to a Final Informal Review Decision dated November 23, 2015.

REASONS FOR RECOMMENDATION

In the present appeal, the Department bore the burden at hearing to demonstrate by a preponderance of evidence that it correctly established the recoupment claim of $970,315.55 against Arnold pursuant to its authority under the MaineCare authorizing statute and regulations. At hearing, the Department described the process by which it reviewed Arnold's billing claims and determined that Arnold had incorrectly billed the Department for certain urine drug screening tests provided for patients participating in its substance abuse treatment programs. Test. of Eva Stewart. In its review, the Department identified 5,218 claims submitted by Arnold for reimbursement from January 1, 2011 to September 17, 2012, which it alleged were billed under the wrong codes. Ex. D-13. As explained in its "Notice of Violation issued on June 5, 2015:

> The claims data shows that AMMC billed and was paid for Urine Drug Testing Codes submitted on a HCFA as well as the encounter code (T1015) on a UB claim form. The correct billing for services would have been for codes T1015 and G0434 to be billed on one UB claim form. Submitting for Urine Drug Testing Codes on a HCFA resulted in an overpayment.

Ex. D-3.

Arnold requested informal review on August 4, 2015, raising several arguments against the allegations in the Notice of Violation, including "fundamental misunderstandings" on the Department's part about "the mechanics of the testing" in relation to "the contemplated scope of RHC Core Services." Ex. D-4. Arnold more specifically raised the following arguments in its August 4, 2015 request:

1. The subject tests were outside the scope of RHC "core services," where they had "no role with respect to diagnosing and treating illness or injury," and thus, could be billed separate from a claim for a single patient encounter/office visit, where the claimed drug screens were "other Medicare defined non-RHC Services."
2. The specific code used by Arnold in billing for the subject tests – i.e. CPT code 80101 – was a proper code for the claimed services throughout the review period of January 1, 2011 to September 17, 2012.

Ex. D-4.

The Department completed its informal review and issued a "Final Informal Review Decision," on November 23, 2015, in which it affirmed its Notice of Violation and recoupment claim for $970,315.55, and provided the following responses to the arguments raised by Arnold in its August 4, 2015 request for informal review:

- Arnold acknowledged the relative simplicity of the claimed drug tests when it coded the claims with a "QW modifier."
- "Simple" or "basic" laboratory tests were within the scope of RHC "core services."
- Arnold routinely billed amounts for $200.00 per claim for its drug screens, which the Department identified as having an actual cost of "$10.00 for the two cassettes."
- Medical necessity for the subject drug tests derived from each test's role in diagnosing and/or treating the "physical illness" of drug addiction.
- Proper coding and claim billing for the subject drug tests, during the review period, would have included two codes submitted on a single UB claim form: a "T1015" RHC encounter code, plus a "G0434" HCPCS code for a low-complexity, "CLIA-waived" test, with a single unit-of-service identified for each multi-drug screen performed.

Ex. D-5.

Arnold perfected its appeal on January 22, 2016. Ex. D-6. With its hearing request, Arnold submitted an amended memorandum in which it raised the following additional arguments against the Department's decision:

1. The subject tests were not part of RHC "core services" because they were not "essential for the *immediate diagnosis and treatment of illness or injury*," but merely necessary "in determining to proceed with ongoing treatment of the patient's drug dependency, which has already been diagnosed and for which the patient is *already undergoing treatment*."
2. Even if the subject tests were part of RHC "core services," Arnold was authorized to bill the Department for the tests independent of RHC "core services" claims on a separate HCFA claim form and with a separate provider billing number, due to the Department's "incorporation by reference" of a 2000 Medicare guidance that authorized fee-for-service claims for "clinical diagnostic services [ ] not within the scope of services covered and paid for under the [Medicare] RHC provisions."
3. Even if the Department had eliminated the availability of CPT code 80101 for certain drug screening tests in 2013 (and replaced with HCPCS code G0434), the subject tests were still outside the scope of "core services" and thus, any recoupment that would flow from mistaken billing would be less than the full amount alleged by the Department.

Ex. D-6 (*emphasis in original*).

The governing regulations and reimbursement principles in place for Rural Health Clinic ["RHC"] services, at the time of the Department's review period, were published within Chapters II and III of the MaineCare Benefits Manual, effective November 24, 2010. *See* 10-144 C.M.R. Ch. 101, sub-Ch. II & III, § 103 (eff. Nov. 29, 2010). A "Rural Health Clinic" was defined as "a Primary Health Care

clinic that is both certified as a Rural Health Clinic by Medicare and enrolled as a MaineCare provider," and included:

A. A provider-based clinic exists when:
   1. the clinic is an integral part of an existing hospital, skilled nursing facility, or home health agency participating in Medicare; and
   2. the clinic is operated with other departments of the provider under common licensure, governance, and professional supervision.

B. An independent clinic is a Rural Health Clinic operating as a separate entity.

10-144 C.M.R. Ch. 101, sub-Ch. II, § 103.01.5 (eff. Nov. 29, 2010).

From January 1, 2011 to September 17, 2012 – the time period of the review at issue here – Departmental regulations identified a range of "covered services" for which RHC providers could bill the Department for reimbursement, chiefly including "core services" defined as:

A. services provided by physicians, physician assistants, advanced practice registered nurses, psychologists, clinical social workers, and clinical professional counselors;

B. services and supplies furnished as incident to services of conditionally, temporarily, fully licensed, otherwise legally recognized or approved practitioners who are designated in Section 103.06-1 of this Manual; and

C. basic laboratory services essential for the immediate diagnosis and treatment of illness or injury, including, but not limited to:
   1. chemical examination of urine by stick or tablet method or both (including urine ketones);
   2. hemoglobin test or hematocrit;
   3. blood sugar test;
   4. examination of stool specimens for occult blood;
   5. pregnancy tests; and
   6. primary culturing for transmittal to a certified laboratory.

Note: To qualify for reimbursement, laboratory services must be in compliance with the rules implementing the Clinical Laboratory Improvement Amendments of 1988 (CLIA "88") and any related amendments.

D. emergency medical care treating life-threatening injuries and acute illnesses, including drugs and biologicals such as:
   1. analgesics
   2. local anesthetics
   3. antibiotics
   4. anticonvulsants
   5. antidotes and emetics
   6. serums and toxoids

E. visiting nurse services (as described in 103.04-4).

10-144 C.M.R. Ch. 101, sub-Ch. II, § 103.04-1 (eff. Nov. 29, 2010).

Departmental regulations also provided that "[p]rovider based clinics are reimbursed in accordance with the Medicare Principles of Reimbursement which apply to the hospital, nursing facility, or home health agency to which the clinic is attached," while "[i]ndependent clinics are reimbursed at a per unit of service rate established by the Medicare fiscal intermediary." 10-144 C.M.R. Ch. 101, sub-Ch. II, § 103.07 (A), (B) (eff. Nov. 29, 2010). With respect to billing, the regulations provided:

> Upon the implementation of MIHMS, providers billing for RHC services must bill using standard CPT and HCPC procedure codes as detailed in Chapter III, Section 103, Table 1. For Core Services, as described under Covered Services-Section 103. 04, providers must bill the code T1015 and include the appropriate revenue codes. When billing, providers must use a UB 04 claim form. Effective October 1, 2010, in addition to billing the code T1015 for Core and Ambulatory Services, providers must also report all services provided including all procedures with the standard CPT and HCPCS codes on the UB 04 claims form for reporting purposes.

10-144 C.M.R. Ch. 101, sub-Ch. II, § 103.09 (eff. Nov. 29, 2010). The same section also provided that "Clinics have the option of obtaining a separate MaineCare provider billing number for the limited purpose of fee-for-service billing and reimbursement for such services as X-ray, EKG, inpatient hospital visits and other Medicare defined non-RHC Services that are billable under Medicare Part B." *Id.* The corresponding, published reimbursement principles identified revenue code "T1015" as the appropriate code to the be used for "Clinic visit/encounter, all inclusive" for "Rural health clinic." 10-144 C.M.R. Ch. 101, sub-Ch. III, § 103 (eff. Nov. 29, 2010).

The Department conceded at hearing that, despite amending Section 103 of the MaineCare regulations in November 29, 2010, it "retained" CPT code 80101 as an active code in its MIHMS[2] online billing system throughout the review period. The Department also conceded that RHC providers, including Arnold, were authorized under the plain language of Section 103 to utilize a separate provider billing number for use in billing for services outside the scope of RHC "core services" that needed to be billed on the "UB 04" claim form under the T1015 RHC encounter code. Thus, the issues remaining in dispute concerned the relative complexity of the subject urine drug screening tests, the scope of the MaineCare regulations' definition of RHC "core services," and the relevance of informal notice from the Department related to the termination and continuing availability of certain billing codes. Those issues are addressed below.

The Subject Urine Drug Screening Tests and RHC "Core Services"

There was no essential dispute between the parties as to the fundamental description of the urine drug screening tests that were the subject of all of the challenged claims included in the Department's review. The subject drug screening tests were "lateral flow chromatographic immunoassays" used to detect evidence of multiple drugs and drug metabolites in urine, and were comprised of plastic cassettes

[2] MIHMS stands for "Maine Integrated Health Management Solution," the Department's online provider claims billing system. *See* "Claims and Billing," Office of MaineCare Services, *available at* http://http://www.maine.gov/dhhs/oms/claims_bill_enroll.html (last visited on Jan. 25, 2017).

featuring multiple test wells and corresponding negative/positive "control regions." Ex. D-17; Ex. D-18; Ex. D-21; Ex. D-27; Ex. A-10. Each single cassette could screen a single patient for as many as 11 drugs or drug metabolites from a single urine sample, and could be performed without the use of any instruments other than those included in the cassette kit. Ex. D-17; Ex. D-18; Ex. D-21; Ex. D-27; Ex. A-10.

At hearing, the Department described the subject tests interchangeably as "simple," "basic," "low complexity," and "CLIA-waived,"[3] referencing the same terms as they appeared in various exhibits admitted into evidence or regulations referenced in argument. Test. of Eva Stewart; Ex. D-5; Ex. D-11; Ex. D-14. The Centers for Medicare and Medicaid Services ["CMS"] and the Food and Drug Administration ["FDA"] co-administer the CLIA program, certifying the quality standards of non-research laboratories that routinely administer non-research testing on humans or human-derived specimens. Ex. D-14; *see* 42 C.F.R. pt. 493 (2016). From this certification program, the federal government assigns relative complexity levels to all such laboratory tests, which are incorporated by reference into a range of government programs including Medicare and Medicaid. *See id.* Under the CLIA regulations, "Laboratory tests are categorized as one of the following: (1) Waived tests; (2) Tests of moderate complexity, including the subcategory of PPM procedures; and (3) Tests of high complexity." 42 C.F.R. § 493.5 (a). These levels are scored based on seven essential criteria:

- knowledge
- training and experience
- reagents and materials preparation
- characteristics of operational steps;
- Calibration, quality control, and proficiency testing materials
- Test system troubleshooting and equipment maintenance
- Interpretation and judgment.

42 C.F.R. § 493.17 (a).[4]

Here, the evidence reflects that the subject urine drug screening tests were CLIA-waived, or low-complexity tests. As noted above, the tests were performed, in simplest terms, in three steps. First, urine was collected into a pipette. Second, three drops of urine were applied from the pipette into each specimen well. Finally, after five minutes, the color line indicators were read to determine whether any of up to 11 drugs or drug metabolites were present in the urine. Ex. D-19; Ex. D-20; Ex. D-21; Ex. D-

[3] The term "CLIA" and "CLIA-waived" relates to the regulations published the Centers for Medicare and Medicaid Services ["CMS"] for the purpose of implementing the Clinical Laboratory Improvement Amendments, 42 U.S.C § 263a. *See* "Standards and Certification: Laboratory Requirements, Ctrs. for Medicare & Medicaid Servs., 42 C.F.R. pt. 493 (2016).

[4] The CLIA regulations further provide:

> Using the seven criteria specified in this paragraph for categorizing tests of moderate or high complexity, each specific laboratory test system, assay, and examination will be graded for level of complexity by assigning scores of 1, 2, or 3 within each criteria. The score of "1" indicates the lowest level of complexity, and the score of "3" indicates the highest level. These scores will be totaled. Test systems, assays or examinations receiving scores of 12 or less will be categorized as moderate complexity, while those receiving scores above 12 will be categorized as high complexity.

Id.

27; Ex. A-10. No other instruments or training were required to perform the tests. Ex. D-19; Ex. D-20; Ex. D-21; Ex. D-27; Ex. A-10.

In its closing argument, Arnold advanced the position that the subject tests were not CLIA-waived, where "significant medical interpretation is called for in order to evaluate the results and determine the future course of treatment and/or testing." Ex. A-15. This argument mischaracterized the functions involved in performing the subject tests, and mistakenly incorporated the post-test treatment provision into the discrete test-taking process. With respect to the former, as noted, test result evaluation required no interpretation, medical or otherwise. Reading the test was a function of observing the presence or non-presence of a colored line next to notations representing each corresponding drug or drug metabolite. Ex. D-19; Ex. D-20; Ex. D-21; Ex. D-27; Ex. A-10. With respect to "determining the future course of treatment and/or testing," this function was not an essential part of the testing but an independent activity. As such, it had no relationship to any of the seven criteria established by CMS in identifying the relative complexity of the subject tests. Applying the CLIA regulations' complexity criteria to these test steps, the lowest level of complexity is reflected in all aspects. Further, the range of sample product descriptions/instruction manuals admitted into evidence fully supports the same finding. Ex. D-19; Ex. D-20; Ex. D-21; Ex. D-27; Ex. A-10.

Finally, it merits noting that Arnold submitted its claims for reimbursement to the Department for the subject tests with the expressed acknowledgement that the subject tests were CLIA-waived. Except for those billed to Medicare for dual eligible patients, every claim identified on the claims spreadsheet attached to the Notice of Violation utilized a CPT code 80101 and a HCPCS code G0434 with an attached "QW modifier." Ex. D-3. The use of a QW modifier with a HCPCS code, like G0434, denoted that the billed laboratory test was a CLIA-waived test. Ex. D-22. In response to the question, "So, is a provider who uses a 80101 code with a QW modifier to make a claim for payment telling the payor, in this case, MaineCare, that they have performed a CLIA-waived test to test for a particular drug?" coding expert Margaret Fortin, testified without hesitation, "Yes." Test. of Margaret Fortin. Based on these factors, it should be found that the subject tests were CLIA-waved, low-complexity tests.

In its Final Informal Review Decision and Notice of Violation, the Department found that the "FDA definition" of a waived test was "the exact same level of complexity as is in the [MaineCare Benefits Manual] policy language ... 'simple' and 'basic.' Ex. D-5. Arnold challenged this equation as "an unreasonable conflation of two pieces of regulatory language that are utterly unrelated," arguing that the difference in the plain language meanings of "simple" and "basic" was sufficiently wide that there was no equivalence. Ex. D-6.

The concept of "basic laboratory services" existed in the context of the Department's identification a non-exhaustive list of examples, "including, but not limited to:

1. chemical examination of urine by stick or tablet method or both (including urine ketones);
2. hemoglobin test or hematocrit;

3. blood sugar test;
4. examination of stool specimens for occult blood;
5. pregnancy tests; and
6. primary culturing for transmittal to a certified laboratory.

10-144 C.M.R. Ch. 101, sub-Ch. II, § 103.04-1 (C) (eff. Nov. 29, 2010).

"Lateral flow chromatographic immunoassay" urine drug screening tests were not specifically listed under Subsection 103.04-1(C), but this fact has far less bearing than the essential comparability of the complexity of such tests to that of the six tests identified in the regulation's non-exhaustive list. As the Department demonstrated at hearing, the complexity factors inherent to a "One-Step Early Pregnancy Test" are nearly identical to those of a "One Step Multi-Drug, Multi-Line Screen Test Device," of the type presented by Arnold as representative of the tests at the heart of this appeal. Ex. D-28; Ex. A-10. Thus, any difference in the plain meaning of the terms "basic," "simple," and "low complexity" is of no consequence where the tests at issue in this appeal were functionally equivalent to those identified as representative examples in RHC core services in Subsection 103.04-1 (C).

Arnold presented a related argument that the term "basic" was only relevant within the context of the full sentence: "basic laboratory services essential for the immediate diagnosis and treatment of illness or injury ...." *See* 10-144 C.M.R. Ch. 101, sub-Ch. II, § 103.04-1 (eff. Nov. 29, 2010). In its January 22, 2016 Memorandum, Arnold argued:

> [T]he most significant element of the definition is that the laboratory service at issue must be "essential for the *immediate diagnosis and treatment of illness or injury* ...." As discussed at length elsewhere in this appeal, the tests at issue are utilized for the purpose of identifying what, if any drugs are present in a patient's urine. The results assist the provider in determining how to proceed with *ongoing* treatment of the patient's drug dependency, which has *already been diagnosed* and for which the patient is *already undergoing treatment.* While drug addiction is indeed a physical illness ... these urine drug screening tests are not related to "immediate" diagnosis and treatment such as that addressed in the RHC core service bundle – rather, they facilitate provider assessment of an adjustment to the ongoing treatment of drug addiction.

Ex. D-6 (*emphasis in original*).

As the Department noted in its Final Informal Review Decision, Section 103 covered services were limited to those defined as "medically necessary." 10-144 C.M.R. Ch. 101, sub-Ch. II, § 103.03. *See also* 10-144 C.M.R. Ch. 101, sub-Ch. I, § 1.02-4 (E) (providing factors used to gauge medical necessity, including an analysis of whether the services are "required for the diagnosis, prevention and/or treatment of illness, disability, infirmity or impairment and which are necessary to improve, restore or maintain health and well-being."). Here, Arnold's parsing of the regulatory definition contradicted its claim to the medical necessity of the urine drug screening tests as well as the direct testimony of its witness, Dr. Steven I. Weisberger. Dr. Weisberger described his clinic's use of drug screening as "a very big part" of his substance addiction treatment practice, where "the way we set-up our program, we see our patients twice a week in the beginning, for at least three months, and each time

we do a urine drug screen." Test. of Steven I. Weisberger, D.O. Arnold's "Patient Rules for Suboxone Program" similarly demonstrated the integral role drug testing has served in its overall program of substance addiction treatment. Ex. A-8. Based on Dr. Weisberger's testimony, it is clear that the clinic would be unable to safely administer the other elements of its substance addiction treatment practice without first assuring that patients have remained compliant with expressed drug abstinence/deferral goals. Test. of Steven I. Weisberger, D.O. More plainly, Arnold could not safely treat a patient with Suboxone without first verifying that the patient has refrained from using other opioids through administration of urine drug screening tests. Test. of Steven I. Weisberger, D.O. As such, it should be found that the urine drug screening tests used by Arnold, are both "basic" and "essential" for the treatment of the illness defined as substance addiction.

Based on the foregoing, it should be concluded that the CLIA-waived, "lateral flow chromatographic immunoassay" urine drug screening tests provided by Arnold during the review period of January 1, 2011 to September 17, 2012, were within the scope of the RHC "core services" identified by Subsection 103.04-1 (C).

Coding and Claims Billing For CLIA-waived Urine Drug Screen Tests

The other primary argument advanced by Arnold at hearing concerned the applicable coding options available to RHC providers seeking reimbursement for tests of the kind at issue in the present appeal during the January 1, 2011 to September 17, 2012 period. Arnold specifically argued that the Department provided authorization to separately bill for the subject tests based on two different theories. First, Arnold argued that the plain language of MaineCare Benefits Manual Subsection 103.09 allowed "separate billing" for "other Medicare defined non-RHC Services that are billable under Medicare Part B," which it alleged included the subject tests. 10-144 C.M.R. Ch. 101, sub-Ch. II, § 103.09. Second, Arnold argued that the Department was barred from seeking recoupment for claims billed with CPT code 80101, where providers were not specifically notified until 2013 that the code had been retroactively eliminated back to December 31, 2009.

In its closing argument, Arnold restated its position with respect to the first of these two arguments: "the separate billing option provided in the MaineCare Benefits Manual at § 103.09 (C), which refers to 'other Medicaid defined non-RHC services', plainly includes all laboratory billing." Ex. A-15. In its closing argument, the Department argued that Arnold's construction of the scope of the applicable Medicare regulations, 42 CFR §§ 491.9, 493.15, was unduly limited, and led to an interpretation of MaineCare Benefits Manual Subsection 103.09 that would impermissibly violate the canon requiring that seemingly contradictory provisions be read "in a way that leaves the efficacy of both intact and achieve a harmonious result."[5] Ex. D-29.

As noted above, the CLIA-waived urine drug screening tests at issue in this appeal were Core Services, for which Section 103.09 provided clear instruction that "providers must bill the code T1015

[5] *Fuhrmann v. Staples Off. Superstore East, Inc.*, 2012 ME 135, ¶29, 58 A.3d 1083, 195.

and include the appropriate revenue codes" and "use a UB 04 claim form." 10-144 C.M.R. Ch. 101, sub-Ch. II, § 103.09. To adopt Arnold's proposed construction would elevate the separate "fee-for-service billing and reimbursement" alternative and render meaningless the strict instruction included in Subsection 103.09 that core services-included procedures having a known HCPC or CPT code must be included with a T1015 encounter code on a single UB 04 claim form. Arnold's proposed construction should be rejected, and the separate "fee-for-service billing and reimbursement" provision should be construed in such a way that limits its application to procedures that are not included in RHC "core services."

Finally, Arnold argued that the Department should be barred from seeking recoupment for claims billed using CPT code 80101, where "MaineCare did not announce to providers that CPT code 80101, which had been used by [Arnold] during the relevant review period, was being discontinued until August 12, 2013." Ex. A-15. As noted above, CPT code 80101 was limited to billing for "moderate" or "high" complexity laboratory tests. Effective November 29, 2010, providers seeking reimbursement for CLIA-waived/low complexity tests were required to bill for such tests as "core services" using the T1015 encounter code, co-listed with a HCPCS G0434 code. Under the terms of its MaineCare provider agreement, Arnold was required to "submit bills in accordance with methods and procedures contained in the [MaineCare Benefits Manual] and billing instructions issued by the Department," and be "responsible for understanding and applying applicable regulations and requirements for proper billing." Ex. D-7. The Department cannot be barred from seeking recoupment of paid claims that were billed in a manner other than that dictated by the regulations in effect at the time, merely because its informal email list serve notice system did not alert providers to changes that took place through the rulemaking process governed by the Maine Administrative Procedures Act. The provision at issue, in Subsection 103.09, was formally promulgated on September 1, 2010, and adopted after notice and comment on November 24, 2010. Ex. D-11. *See also* 10-144 C.M.R. Ch. 101, sub-Ch. II & III, § 103 (Proposed Sept. 7, 2010).[6] Arnold did not allege, and the record does not include any evidence of any notice infirmity inherent to the rulemaking process that resulted in adoption of the November 24, 2010 final rule. Any reliance Arnold placed upon the Department's silence about code changes through its informal email list serve was not reasonable, where the Department provided formal notice through the rulemaking that effectuated the changes underlying the alleged violation. *See Dep't of Human Servs. v. Bell*, 1998 ME 123, ¶8, 711 A.2d 1292, 1295 (Requiring "clear and satisfactory proof" that a government entity was silent when it "had a duty to speak" before that that entity can be equitably estopped.). *See also Dep't of Health and Human Servs. v. Pelletier*, 2009 ME 11, ¶17, 964 A.2d 630, 635 (elements of equitable estoppel against a government entity); *Mrs. T. v. Comm'r of Dep't of Health and Human Servs.*, 2012 ME 13, ¶9, 36 A.3d 888, 891 (party asserting equitable estoppel defense has the burden of proof). As such, it should be concluded that any reliance Arnold placed upon the lack of informal list serve

[6] The final rule adopted on November 24, 2010 removed language in Subsection 103.09 that included claim filing instructions for providers to follow through several steps of the implementation of the MIHMS online billing system, and replaced the provisions with the requirement to bill for "core services" on the UB 04 claims form with code T1015 and all applicable procedure codes. *Id. See also* 10-144 C.M.R. Ch. 101, sub-Ch. II & III, § 103 (eff. Sept. 1, 2010).

instruction about its obligation to bill in the manner required by Subsection 103.09 should not defeat the Department's ability to recoup for overpayments directly linked to wrongly billed claims.

For these reasons, the Hearing Officer recommends that it be concluded that the Department was **correct** when it determined, for the review period of January 1, 2011 to September 17, 2012, Arnold Memorial Medical Center was overpaid $970,315.55, pursuant to a Final Informal Review Decision dated November 23, 2015.

MANUAL CITATIONS

- DHHS Administrative Hearing Regulations, 10-144 C.M.R. Ch. 1, § VII (2016)
- MaineCare Benefits Manual, 10-144 C.M.R. Ch. 101 (eff. Jan. 1, 2010).

RIGHT TO FILE RESPONSES AND EXCEPTIONS

THE PARTIES MAY FILE WRITTEN RESPONSES AND EXCEPTIONS TO THE ABOVE RECOMMENDATIONS. ANY WRITTEN RESPONSES AND EXCEPTIONS MUST BE RECEIVED BY THE DIVISION OF ADMINISTRATIVE HEARINGS WITHIN FIFTEEN (15) CALENDAR DAYS OF THE DATE OF MAILING OF THIS RECOMMENDED DECISION.

A REASONABLE EXTENSION OF TIME TO FILE EXCEPTIONS AND RESPONSES MAY BE GRANTED BY THE CHIEF ADMINISTRATIVE HEARING OFFICER FOR GOOD CAUSE SHOWN OR IF ALL PARTIES ARE IN AGREEMENT. RESPONSES AND EXCEPTIONS SHOULD BE FILED WITH THE DIVISION OF ADMINISTRATIVE HEARINGS, 11 STATE HOUSE STATION, AUGUSTA, ME 04333-0011. COPIES OF WRITTEN RESPONSES AND EXCEPTIONS MUST BE PROVIDED TO ALL PARTIES. THE COMMISSIONER WILL MAKE THE FINAL DECISION IN THIS MATTER.

CONFIDENTIALITY

THE INFORMATION CONTAINED IN THIS DECISION IS CONFIDENTIAL. ***See*** **42 U.S.C. § 1396a (a)(7); 22 M.R.S. § 42 (2); 22 M.R.S. § 1828 (1)(A); 42 C.F.R. § 431.304; 10-144 C.M.R. Ch. 101 (I), § 1.03-5. ANY UNAUTHORIZED DISCLOSURE OR DISTRIBUTION IS PROHIBITED.**

Dated: 1/25/17

Richard W. Thackeray, Jr.
Administrative Hearing Officer

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