

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA**

UNITED STATES OF AMERICA, et al.,

ex rel. TINA D. GROAT,

Plaintiffs,

v.

BOSTON HEART DIAGNOSTICS
CORPORATION,

Defendant.

Civil Action No. 15-487 (RBW)

MEMORANDUM OPINION

The plaintiff/relator, Tina D. Groat, M.D., brings this qui tam action against the defendant, Boston Heart Diagnostics Corporation (“Boston Heart”), under the federal False Claims Act, 31 U.S.C. § 3729 (2012), and various analog state false claims statutes. See Relator’s Second Amended Complaint Pursuant to the Federal False Claims Act, 31 U.S.C. §§ 3729 et seq. and Pendent State False Claims Acts (“2d Am. Compl.”) ¶ 1. Currently before the Court are the Relator’s Motion for Judicial Notice (“Relator’s Mot.”) and Boston Heart Diagnostics Corporation’s Motion to Dismiss Relator’s Second Amended Complaint (“Def.’s Mot.”), which seeks dismissal of the plaintiff’s Second Amended Complaint pursuant to Federal Rules of Civil Procedure 9(b) and 12(b)(6). See Def.’s Mot. at 2. Upon careful consideration of the parties’ submissions,¹ the Court concludes that it must grant the relator’s motion for judicial notice and grant in part and deny in part Boston Heart’s motion to dismiss.

¹ In addition to the filings already identified, the Court considered the following submissions in rendering its decision: (1) the Memorandum of Law in Support of Boston Heart Diagnostics Corporation’s Motion to Dismiss
(continued . . .)

I. BACKGROUND

A. Statutory Background

A brief overview of the Medicare program will help elucidate the relator's allegations in this case. Medicare is a federal health insurance program for the elderly and people with disabilities. See 42 U.S.C. § 1395c (2012). Medicare Part B, which provides outpatient coverage for, among other things, diagnostic laboratory tests, see 42 C.F.R. § 410.32 (2016), only covers medical services that are "reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member," 42 U.S.C. § 1395y(a)(1)(A). "[Laboratory t]ests that are performed in the absence of signs, symptoms, complaints, personal history of disease, or injury are not covered except when there is a statutory provision that explicitly covers tests for screening as described." Medicare Claims Processing Manual: Chapter 16—Laboratory Services § 120.1, available at <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104C16.pdf> (last visited May 16, 2017).

Medicare establishes its national payment policy for covered items or services through national coverage determinations, which are formal decisions by the Secretary of Health and Human Services regarding whether, and under what circumstances, Medicare covers a particular item or service. See 42 U.S.C. § 1395ff(1); 42 C.F.R. § 405.1060(a). National coverage determinations are binding on both Medicare contractors and administrative law judges, who preside over Medicare coverage appeals. See 42 U.S.C. § 1395ff(1)(A)(i); 42 C.F.R.

(. . . continued)

Relator's Second Amended Complaint ("Def.'s Mem."); (2) the Relator's Oppos[i]tion to Defendant's Motion to Dismiss Relator's Second Amended Complaint ("Relator's Opp'n"); and (3) Boston Heart Diagnostics Corporation's Reply in Support of its Motion to Dismiss Relator's Second Amended Complaint ("Def.'s Reply").

§ 405.1060(a). Medicare contractors process and pay Medicare claims within a specified jurisdiction on behalf of the Centers for Medicare and Medicaid Services (“CMS”), and have authority to issue local coverage determinations for that jurisdiction. See 42 U.S.C. § 1395ff(f)(2); see also id. § 1395m-1(g)(noting that Medicare contractors may issue local coverage determinations regarding clinical diagnostic laboratory tests under the same process). Local coverage determinations, like national coverage determinations, govern Medicare coverage for a particular item or service. See id. § 1395ff(f)(2)(b). Administrative law judges “give substantial deference” to local coverage determinations, but they are not bound by them. 42 C.F.R. § 405.1062.

An entity seeking reimbursement for services provided to Medicare patients must submit a CMS-1500 form to the Medicare contractor. See United States ex rel. Hobbs v. MedQuest Assocs., Inc., 711 F.3d 707, 711 (6th Cir. 2013). “The[CMS-1500] form[] reflect[s] the treatment or services provided and identif[ies] the [entity that] provided them. Tests, supplies, and services are correlated to a series of unique numbers, called CPT codes, which quickly convey to the [claims processor] what reimbursable expenses the [entity] has incurred.” Id. at 711. The CMS-1500 form requires the entity to certify that, among other things, “the services on this form were medically necessary.” Health Insurance Claim Form (“CMS-1500”) at 2, available at <https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/Downloads/CMS1500.pdf> (last visited May 16, 2017).

B. Factual Background and Procedural History

The relator is a medical doctor and the National Medical Director of Women’s Health and Genetics at United Healthcare (“United”), 2d Am. Compl. ¶ 6, which is a health insurance company that offers Medicare and Medicaid insurance coverage, TriCare health insurance

