UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA and THE COMMONWEALTH OF MASSACHUSETTS, EX REL JULIO ESCOBAR, and CARMEN CORREA, ADMINISTRATRIX OF THE ESTATE OF YARUSHKA RIVERA	)	
Plaintiffs,	)	CIVIL ACTION NO. 11-11170-DPW
v.	)	
UNIVERSAL HEALTH SERVICES, INC.,	)	
Defendant.	)	

MEMORANDUM AND ORDER
March 26, 2014

Plaintiffs-Relators Julio Escobar and Carmen Correa, as administratrix of the estate of their daughter, Yarushka Rivera, initially brought this *qui tam* action on behalf of the United States and the Commonwealth of Massachusetts alleging that Defendant Universal Health Services, Inc. violated the False Claims Act ("FCA"), 31 U.S.C. § 3729, and the Massachusetts False Claims Act ("MFCA"), M.G.L. 12 § 5A. The government having declined to intervene, the Plaintiffs are now pursuing the case directly.

The Plaintiffs allege Universal violated the FCA and MFCA by submitting claims for reimbursement to the government despite non-compliance with various Massachusetts regulations. Plaintiffs argue that the claims Universal submitted for reimbursement to the Medicaid program, MassHealth, were false

because Universal was systematically violating Massachusetts health regulations regarding patient care, supervision, and core staffing requirements.

Universal moves to dismiss the operative pleading – Plaintiffs' Second Amended Complaint – arguing that the FCA and MFCA prohibit fraud on the government and, absent such fraud, are not the appropriate vehicles for policing general regulatory compliance or providing a cause of action to injured plaintiffs. Universal contends that violations of the regulations at issue in this case are not preconditions of payment and are simply not actionable under the FCA or MFCA. I will grant Defendant's motion.

I. FACTUAL CONTEXT

Universal Health Services owns and operates various health care facilities throughout Massachusetts. (Second Amended Complaint ¶¶ 5-7.) The facility at issue in this litigation is the Arbour Counseling Services clinic in Lawrence, Massachusetts. (*Id.*) It is a mental health center operating as a satellite clinic of the location in Malden, Massachusetts. (*See* Second Amended Complaint, Ex. 15 at 1.) It also participates in MassHealth, the Medicaid program for low-income and disabled residents of Massachusetts. (*Id.* ¶¶ 1, 8.)

Plaintiffs-Relators are the parents of Yarushka Rivera, who died of a seizure in October 2009 while in the care of the

Lawrence Arbour Counseling Services facility, and whose treatment forms the central thrust of this action. (Second Amended Complaint ¶¶ 21, 113-14.)

Plaintiffs' Second Amended Complaint asserts 14 claims against United. Counts I-IV allege violations of the Federal False Claims Act for reimbursement requests United filed for services by those who treated Ms. Rivera: Maria Pereyra, Diane Casado, Anna Fuchu, and Maribel Ortiz. (*See* Second Amended Complaint ¶¶ 198-251.) Counts VIII-XI allege violations of the Massachusetts False Claims Act for the same reimbursement requests as in Counts I-IV. (*See* Second Amended Complaint ¶¶ 293-343.) Counts V-VI and Counts XII-XIII allege violations of the FCA and MFCA, respectively, for reimbursement requests for unnamed other clinical staff and nurse practitioners. (*See* Second Amended Complaint ¶¶ 252-275, 344-363.) Finally, Counts VII and XIV allege violations of the FCA and MFCA, respectively, for reimbursement requests despite improper staffing and supervision. (*See* Second Amended Complaint ¶¶ 276-292, 364-378.)

A. Medical Care

The common thread running through each of Plaintiffs' claims is the allegation that the reimbursement requests were fraudulent because United was violating MassHealth regulations regarding qualifications, staffing, and supervision. None of the claims allege liability on the basis of a low quality of medical care;

such claims would not be actionable under either the FCA or the MFCA. *See United States ex rel. Rost* v. *Pfizer, Inc.*, 507 F.3d 720, 727 (1st Cir. 2007)("FCA liability does not attach to violations of federal law or regulations . . . that are independent of any false claim."), *abrogated on other grounds by Allison Engine Co.* v. *United States ex rel. Sanders*, 553 U.S. 662 (2008). Nevertheless, Plaintiffs dedicate numerous paragraphs and pages to detailing Ms. Rivera's medical treatment history at the Lawrence Arbour Counseling Services. I recount that history as context for the relevant factual allegations regarding false claims.

When Ms. Rivera began experiencing behavioral problems in middle school in 2004, she was referred to Arbour for counseling (Second Amended Complaint ¶ 23.) Eventually Arbour assigned Maria Pereyra to be Ms. Rivera's counselor. (Second Amended Complaint ¶ 28.) Diana Casado took over Ms. Rivera's care in 2008. (Second Amended Complaint ¶ 51.) Neither Ms. Pereyra nor Ms. Casado has any professional license. (Second Amended Complaint ¶¶ 30, 53.) In February 2009, Anna Fuchu took over Ms. Rivera's care and diagnosed her with bi-polar disorder. (Second Amended Complaint ¶¶ 64, 71.) Anna Fuchu has a doctorate in psychology, but is not board certified at least in part because her degree is from Southern California University, an internet college that the Board of Licensure does not recognize. (Second

Amended Complaint ¶¶ 66-67, 144.) A few months later, in May 2009, Ms. Rivera met with Maribel Ortiz, a nurse practitioner who prescribed Trileptal for Ms. Rivera's bi-polar disorder. (Second Amended Complaint ¶¶ 84-85.) Trileptal is an anti-seizure medication and off-label treatment for bi-polar disorder.

Plaintiffs attempted to contact Ms. Ortiz and left messages for her on May 7 and 8, 2009 when Ms. Rivera had an adverse reaction to the Trileptal. (Second Amended Complaint ¶¶ 88-89.) Before having heard back from Ms. Ortiz, Ms. Rivera voluntarily stopped taking the Trileptal. (Second Amended Complaint ¶ 90.) She then had a seizure less than a week later although she had no prior history of seizures. (Second Amended Complaint ¶ 92-93.) Withdrawal resulting from abruptly ceasing Trileptal can cause seizures. (Second Amended Complaint ¶ 94.) Plaintiffs allege that approximately five months later, in October 2009, Ms. Rivera died of a seizure, but Plaintiffs make no allegations specifically connecting her death or her seizure in October with her treatment at Arbour. (Second Amended Complaint ¶ 114.)

Plaintiffs profess that they were confused regarding the qualifications of the four individuals assigned to treat their daughter, (*see* Second Amended Complaint ¶¶ 29-30, 52-53, 83), however Plaintiffs' confusion is not relevant to whether United made any false claims to MassHealth. The relevant factual consideration is that Arbour billed MassHealth for services that

Pererya, Casado, Fuchu, and Ortiz performed. (Second Amended Complaint ¶¶ 41-49, 58-62, 72-76, 100-112.) Plaintiffs allege that Pererya, Casado, Fuchu, and Ortiz were not qualified to perform the Health services they offered nor were they adequately supervised. The only physician on Arbour's staff was Maria Gaticales, a psychiatrist who is not board certified. (Second Amended Complaint ¶ 108-109.) Plaintiffs also allege that Dr. Gaticales did not properly supervise the rest of the staff, as required by Massachusetts regulations but only involved herself in patients' care when the direct providers ask for her help. (Second Amended Complaint ¶ 87.)

B. History of Plaintiff-Relator's Complaints

The history of this action has been protracted. It involves numerous complaints, amendments, supplements, and other pleading documents with multiple regulatory agencies and this court spanning from Plaintiff's first regulatory complaint in December 2009 to the operative pleading in this case, filed February 2013.

1. Regulatory Complaints

Plaintiffs filed complaints with a variety of agencies including the Massachusetts Division of Professional Licensure ("DPL"), (*see, e.g.*, Second Amended Complaint ¶¶ 137, 142), the Disabled Persons Protection Commission ("DPPC"), (*see* Second Amended Complaint ¶¶ 122-136), and the Department of Public Health ("DPH"), (*see* Second Amended Complaint ¶¶ 134-179).

Plaintiffs filed three separate complaints with the DPL, one on October 25, 2010, one on November 3, 2010, and one on January 8, 2011. (*See* Second Amended Complaint ¶¶ 137, 142, 147). Plaintiffs filed complaints and supplementary pleadings with the DPPC in December 2009 and May 2010, and then filed a new complaint in December 2010. (*See* Second Amended Complaint ¶¶ 122, 127, 129, 146.) Plaintiffs also filed two separate complaints with the DPH, one on August 7, 2010 and another on February 7, 2011. (*See* Second Amended Complaint ¶¶ 134, 148.)

The DPL entered into a consent decree with Mr. Keohan, Arbour's Clinical Director, in which Mr. Keohan agreed to a two-year period of supervised probation. (*See* Second Amended Complaint ¶¶ 175-177.) It also entered into a consent decree with Ms. Fuchu who paid a $1,000 penalty and agreed not to refer to herself as a "psychologist" so long as she remained unlicensed. (*See* Second Amended Complaint ¶ 178, Ex. 14.)

The DPPC concluded that Ms. Ortiz did not have proper supervision as required under Massachusetts regulations. (*See* Second Amended Complaint ¶ 163; Ex. 11, 12.) It also found that none of the four people directly treating Ms. Rivera engaged in any abuse. (*See* Second Amended Complaint ¶¶ 165, 174.)

The DPH concluded that the four people treating Ms. Rivera were not qualified to do so unsupervised, and that Dr. Gaticales did not - and, in fact, was not qualified to - provide the

required supervision. (*See* Second Amended Complaint ¶¶ 183-185, Ex. 15.) DPH made specific findings that the Arbour Clinic was in violation of a number of regulations, including (1) 105 C.M.R. 140.530(c)(1)(a), requiring a board-certified psychiatrist on staff; (2) 105 C.M.R. 140.530(D)(3)(c), requiring the staff psychiatrist to participate in interdisciplinary case team reviews; and (3) 105 C.M.R. 140.530(C), requiring those without certain qualifications or licenses to be "supervised on a regular basis by professional staff members." (*See* Second Amended Complaint ¶¶ 187, 189-190.)

2. District Court Complaints

Plaintiffs filed their first FCA and MFCA action in this court on July 1, 2011. In February and March 2012, the United States and the Commonwealth of Massachusetts determined that they would not intervene, and I unsealed the case. Plaintiffs failed to serve the complaint on United within the required, four-month time frame. Five months after the case was unsealed, Plaintiffs amended the Complaint. The new complaint removed claims that Arbour's clinicians were not licensed, which is not a potential regulatory violation, and instead asserted that the Arbor staff did not have proper supervision for its unlicensed personnel.

United moved to dismiss the amended complaint. At the motion hearing on January 24, 2013, after substantial argument in which Plaintiffs relied on documents and allegations outside the

amended complaint to explain which regulations and regulatory violations constituted false claims, Plaintiffs' counsel requested further leave to amend the complaint one final time in order to include the relevant regulatory allegations in the operative complaint itself - a document I may consider on a motion to dismiss - rather than in affidavits and briefs - documents I cannot consider as the source of factual allegations at this stage. I granted this request on the understanding that Plaintiffs must be willing to rise or fall on their new Complaint. Plaintiff filed the Second Amended Complaint on February 25, 2013. United filed a new motion to dismiss on March 22, 2013 and I held another motion hearing.

II. STANDARD OF REVIEW

To survive a motion to dismiss, "a complaint must contain sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face." *Ashcroft* v. *Iqbal*, 556 U.S. 662, 678 (2009) (internal citation omitted). "'Naked assertion[s]' devoid of 'further factual enhancement'" do not constitute adequate pleading. *Id.* (quoting *Bell Atl. Corp.* v. *Twombly*, 550 U.S. 544, 557 (2007)). All well-pleaded factual allegations in the complaint must be taken as true and all reasonable inferences must be drawn in the pleader's favor. *SEC* v. *Tambone*, 597 F.3d 436, 441 (1st Cir. 2010) (en banc). However, "conclusory allegations" and "bare assertions . . .

amount[ing] to nothing more than a 'formulaic recitation of the elements'" are not entitled to the presumption of truth. *Iqbal*, 556 U.S. at 681 (quoting *Twombly*, 550 U.S. at 555). Unless the alleged facts push a claim "across the line from conceivable to plausible," the complaint is subject to dismissal. *Iqbal*, 556 U.S. at 680.

Federal Rule of Civil Procedure 9(b) requires that cases sounding in fraud or mistake, such as claims under the FCA and MFCA, must also "state with particularity the circumstances constituting fraud or mistake."

III. DISCUSSION

To state a claim under the FCA, Plaintiffs must allege that United "knowingly present[ed], or cause[d] to be presented, a false or fraudulent claim for payment or approval." 31 U.S.C. § 3729(a)(1)(A); *see also U.S. ex rel. Eisenstein* v. *City of New York*, 556 U.S. 928, 930 (2009). The false claim must also be material to the government's payment decision. *See U.S. ex rel. Loughren* v. *Unum Group*, 613 F.3d 300, 307 (1st Cir. 2010). A claim is material if it "has a natural tendency to influence, or is capable of influencing, the decision of the decision making body to which it is addressed." *Id.* at 309 (citations and quotations omitted). Because the MCFA prohibits the same conduct as the FCA and is "similarly worded," the two must be "construed consistently." *See New York* v. *Amgen Inc.*, 652 F.3d 103, 109

(1st Cir. 2011); *Scannell* v. *AG*, 872 N.E.2d 1136, 1138 n. 4 (Mass. App. Ct. 2007).

The dispute between the Plaintiffs and Defendants regarding the viability of the claims asserted in the Second Amended Complaint amounts largely to a disagreement regarding the implications of the First Circuit's decision in *United States ex rel. Hutcheson* v. *Blackstone Medical, Inc.*, 647 F.3d 377, 385 (1st Cir. 2011), *cert. denied* 132 S.Ct. 815 (2011), as well as the subsequent decisions in *New York* v. *Amgen*, 652 F.3d 103, and *United States ex rel. Jones* v. *Brigham & Women's Hosp.*, 678 F.3d 72, 85-86 (1st Cir. 2012).

In those cases, the First Circuit repeatedly confirmed that it does not recognize what it has deemed to be the "artificial categories" of false claims used by other circuits, such as "legally false" as compared with "factually false" or "express certification" as compared with "implied certification." *See Hutcheson*, 647 F.3d at 380, 385. *See also Amgen*, 652 F.3d at 108-09; *Brigham & Women's Hosp.*, 678 F.3d at 85-86. While this line of case law makes clear that courts within this Circuit are not to use formal categories to trigger specific tests or requirements for claims under the FCA, *see Hutcheson*, 647 F.3d at 386, the First Circuit has not fully identified the proper test in the absence of a categorical approach.

The Plaintiffs argue that, along with its rejection of the distinction between "legally false" and "factually false" or "express certification" and "implied certification," the First Circuit has also abandoned the distinctions between conditions of payment and conditions of participation for purposes of the FCA. Plaintiffs allege that United's claims for reimbursement were false because every request for reimbursement carries with it the implication that Arbour has complied with applicable regulations. In lieu of the distinction between conditions of payment and conditions of participation, Plaintiffs argue that the relevant inquiry focuses only on whether Arbour's "systematic failure to comply with Mass.Heath regulations relating to patient care, supervision and core staff . . . [may] potentially be deemed material to Mass.Health's decision whether to pay for those services."

United argues that the distinction between conditions of payment and conditions of participation survive *Hutcheson*, *Amgen*, and *Brigham & Women's Hosp.*, and that no claims were false because the only regulations Arbour violated - and therefore the only regulations with which reimbursement claims might have represented compliance - were conditions of participation, but not conditions of payment.

The parties also dispute whether Arbour's regulatory violations were sufficiently problematic to be material to the

government's decision to reimburse, as required by the FCA, and whether Plaintiffs' claims should be dismissed either for failure to effectuate service in the time required or under the public disclosure bar.

A. Falsity

Although the First Circuit has rejected certain distinctions in FCA analysis as artificial, I am of the view that the distinction between conditions of payment and conditions of participation survives the *Hutcheson* line of case law.

In *Hutcheson*, the First Circuit specifically rejected the District Court's holding that in instances of implied legal misrepresentation, the statute or regulation must *expressly* state that it is a precondition of payment. *See Hutcheson*, 647 F.3d at 386. It did not, however, reject the District Court's underlying assumption that a claim is false under the FCA for misrepresenting compliance with regulations only if the regulation is a precondition of payment--whether express or implied. *Id.* at 392. Rather, it repeatedly made clear that violation of a condition of payment was a necessary fact upon which it relied in order to find that the Plaintiff stated a claim: "[W]e hold that Hutcheson's complaint, in alleging that the hospital and physician claims represented compliance with a material condition of payment that was not in fact met, states a claim under the FCA that the hospital and physician claims for

payment at issue in this case were materially false or fraudulent." *Hutcheson*, 647 F.3d at 379. *See also id.* at 392 ("We first address whether the claims at issue here misrepresented compliance with a *precondition of payment* so as to be false or fraudulent . . . ." (Emphasis added)).

In *Amgen*, the First Circuit described the showing necessary for the plaintiffs to state a claim--and made explicit that the plaintiffs must allege misrepresentation of a "material precondition of Medicaid payment." 652 F.3d at 110 ("To survive this 12(b)(6) motion, [plaintiffs] . . . must show that the claims at issue in this litigation misrepresented compliance with a material *precondition of Medicaid payment* such that they were false or fraudulent." (Emphasis added)). In seeking dismissal of the relators' claims, the defendants argued that the plaintiffs "ignored the difference between conditions on participation in Medicaid and conditions on payment." *Id.* at 113. The First Circuit did not reject the condition of payment/condition of participation dichotomy set forth by the defendant, but instead accepted it and performed its analysis under that rubric. Under that analysis, the First Circuit held that the relevant provision was a condition of payment, rather than only of participation. *Id.* ("This distinction . . . is not relevant to the provisions . . . which explicitly refer to payment.").

As the First Circuit has earlier explained, not every regulatory violation gives rise to a potential FCA action. *See Rost*, 507 F.3d at 727 ("FCA liability does not attach to violations of federal law or regulations . . . that are independent of any false claim."). A plaintiff may not use the FCA to act as an ombudsman for compliance with regulatory requirements that do not necessarily impact government payment. The FCA concerns itself exclusively with fraud and false statements to the government, leaving general regulatory compliance and compliance with regulations that do not bear on the government's obligation to pay reimbursement to other enforcement mechanisms. *See id.* As I have observed, it is my understanding that in *Hutcheson* "[t]he First Circuit . . . reaffirmed that satisfaction of this element [of a false or fraudulent claim] requires a showing that compliance with the underlying contract, statute or regulation, constitutes a 'precondition of payment' by the Government 'that had not been met.'" *United States ex rel. Dyer* v. *Raytheon Co.*, 2011 WL 3294489, at *9 (D. Mass. July 29, 2011) (quoting *Hutcheson*, 647 F.3d at 392). Violations of only a condition of participation will not suffice.[1]

[1] Courts in other circuits have reached this same conclusion. *See e.g.*, *United States ex rel. Hobbs* v. *Medquest Associates, Inc.*, 711 F.3d 707, 714 (6th Cir. 2013) ("The success of a false certification claim depends on whether it is based on 'conditions of participation' in the Medicare program (which do not support

To be sure, the regulation need not expressly state that it is a condition of payment in order to lay the foundation for FCA liability, and the two categories are not necessarily mutually exclusive - a precondition of participation may *also* be a precondition of payment - but before a regulation can give rise to FCA liability, it must, in fact, be a condition of payment.

Plaintiffs allege that Arbour violated a number of Massachusetts regulations. Specifically, Plaintiffs allege that Arbour violated 130 C.M.R. §§ 429.424; 429.423(D); 429.437; and 429.408. (*See* Second Amended Complaint ¶ 10.) They also reference 130 C.M.R. § 429.439 for the proposition that some supervision requirements are pre-conditions to payment, and 130 C.M.R. § 429.422 for the staffing requirements at a mental health center. (*See id*. ¶ 12.) Finally, despite Plaintiffs' request for leave to file a Second Amended Complaint in order to include allegations of the specific regulations they contend Arbour violated in the complaint itself rather than rely on extrinsic documents, Plaintiffs again raise a handful of new regulations in their opposition brief, including 105 C.M.R. § 140.313, 140.520, and 140.430, as well as 243 C.M.R. § 2.10(4). I address each in turn.

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an FCA claim) or on 'conditions of payment' from Medicare funds (which do support FCA claims)."); *Mikes* v. *Straus*, 274 F.3d 687, 697 (2d Cir. 2001) ("[A] claim under the Act is legally false only where a party certifies compliance with a statute or regulation as a condition to governmental payment.").

1. 130 C.M.R. §§ 429.000 *et seq.*

The majority of the regulations that Plaintiffs allege Defendant violated appear in Title 130 of the Code of Massachusetts Regulations, entitled "Division of Medical Assistance," Chapter 429.000, entitled "Mental Health Center Services." By its own terms, Chapter 429.000 generally does not establish preconditions to payment. Rather, it specifically states that "130 CMR 429.000 establishes requirements for *participation* of mental health centers in MassHealth . . . ." 130 C.M.R. § 429.401 (emphasis added). *Compare* 130 C.M.R. § 450.231 (setting out the "General Conditions of *Payments*" (emphasis added)). Although a statement in a preamble or introduction cannot contradict or control the plain language of the substantive portions of the regulation, it can provide useful guidance in the construction of ambiguous clauses. *Cf. Brennan* v. *The Governor*, 540 N.E.2d 685, 688 (Mass. 1989) ("Statements regarding the scope or purpose of an act that appear in its preamble may aid the construction of doubtful clauses, but they cannot control the plain provisions of the statute."). Because the introduction to Chapter 429.000 specifically states that it "establishes requirements for participation," I view any section of this chapter through the lens of this language unless its "plain provisions" suggest that it is also a precondition of payment.

First, § 429.424 generally sets out the required qualifications for various staff members including psychiatrist, psychologist, counselors, nurses, and others. Plaintiffs base Counts I-III, V, VIII-X, and XII, the supervision-related claims, on alleged violations of § 429.424(E).

Section 429.424(E)(1) provides that "unlicensed staff . . . must be under the direct and continuous supervision of a fully qualified professional staff member trained in one of the core disciplines described in 130 C.M.R. § 429.424(A) through (D)." Plaintiffs allege that the unlicensed staff at Arbour did not have the required supervision. However, because § 429.424 contains no indication that it is a precondition of payment, and because the introduction to this Chapter of the Massachusetts Code of Regulations states that it sets forth conditions of participation, I find that § 429.424(E) is not a precondition of payment and cannot form the foundation for an FCA claim.

Second, §§ 429.424(A) and (B) set out the qualifications for psychiatrists and psychologists, respectively, who provide services at mental health centers. Section 429.423(D) sets out the responsibilities of a mental health center psychiatrist. Plaintiffs allege that United violated these sections because the Arbour clinic in Lawrence did not employ a licensed psychologist or a board certified or board-eligible psychiatrist. Plaintiffs base Counts VII and XIV, the staffing-related claims, on the

alleged violations of § 429.424 (A) and (B) as well as § 429.423(D). These allegations fail for multiple reasons.

Although §§ 429.424(A)-(B), and 429.423(D) set out the required qualifications in the event Arbour decides to employ certain professionals, they do not describe which professionals Arbour must employ. The actual staffing requirements appear in § 429.422, which states that "Dependent satellite programs must employ at least two full-time equivalent professional staff members from separate nonphysician core disciplines" and any autonomous satellite programs must comply with § 429.423 and the general requirements for an independent mental health center in § 429.422(A)-(C). The regulations distinguish between two kinds of Satellite programs: Dependent Satellite Programs and Autonomous Satellite Programs. *See* 130 C.M.R. § 429.402 (defining a "Dependent Satellite Program" as "a mental health center program in a satellite facility that is under the direct clinical management of the parent center" and an "Autonomous Satellite Program" as "a mental health center program operated by a satellite facility with sufficient staff and services to substantially assume its own clinical management independent of the parent center."). Plaintiffs do not allege that the Arbour location in Lawrence is an autonomous satellite program, nor do they allege that it failed to employ two "full-time equivalent professional[s] . . . from separate nonphysician core

disciplines." 130 C.M.R. § 429.422(D). Plaintiffs have therefore not plead sufficient facts to raise a plausible violation of any staffing requirements.

Even if I were to consider Plaintiffs' failure to allege whether Arbour is an autonomous or dependent program to be some kind of latent, implied form of alternative pleading rather than a failure to plead a plausible claim, Plaintiffs' staffing-related claims fail for the independent reason that nothing contained in any of §§ 429.424(A)-(B), 429.423(D), or 429.422 indicates that they are conditions of payment, and because the introduction to Chapter 429.000 states that it sets out conditions of participation, I therefore find that they are merely conditions of participation and cannot support FCA claims.

Third, § 429.437 requires that a mental health center have and observe written procedures. It also specifies the requirements for such a written policy. *See* 130 C.M.R. § 429.437. Although the Second Amended Complaint includes this section among the regulations it lists, it contains no factual allegations regarding the presence of absence of any written policy. Plaintiffs have therefore failed to raise any plausible claim based on this section. Furthermore, § 429.437 cannot sustain an FCA claim for the independent reason that it, too, falls within the general description of Chapter 429.000 as a condition of participation and contains no indication that it

might - notwithstanding the introduction - be a precondition of payment.

Fourth, § 429.408 describes administrative considerations for reimbursement. In relevant part, it specifies that "[p]ayment by the MassHealth agency for a mental health service includes payment for . . . all aspects of service delivery [including] . . . (3) supervision or consultation with another staff member . . . ." 130 C.M.R. § 429.408(c). Plaintiffs argue that because MassHealth includes the costs of supervision in its payments and because Arbour did not provide adequate supervision, Arbour must have submitted claims for reimbursement for services it did not perform. *See United States* v. *Cathedral Rock Corp.*, No. 03-cv-1090, 2007 WL 4270784, *6 (E.D. Mo. Nov. 30, 2007) ("In a worthless services claim, the performance of the service is so deficient that for all practical purposes it is the equivalent of no performance at all. . . . This doctrine has been recognized as a basis for relief under the civil False Claims Act." (citations omitted)). However, Defendant could not have specifically violated this regulation because it neither requires any particular action, nor does it prohibit any particular conduct. It merely describes certain kinds of services for which MassHealth pays. *See id.* In order for this regulation to form the basis for a false claim, Plaintiffs must allege that Defendant violated some other regulation that is a precondition

of payment and which implicates § 429.408. They have not and cannot do so. As discussed above, Plaintiffs have neither adequately alleged any violation of the supervision regulations, nor are such regulations preconditions of payment. Even though the costs of supervision are included in the reimbursement MassHealth provides, *see* 130 C.M.R. § 429.408(C)(3), compliance with the supervision requirements are not preconditions of payment and therefore cannot form the basis of an FCA claim.

Finally, the only section of Chapter 429.000 whose "plain provisions" indicate that it is a condition of payment is 130 C.M.R. § 429.439. It states that "[s]ervices provided by a satellite program are reimbursable only if the program meets the standards described below." 130 C.M.R. § 429.439. This section lists four standards, labeled A-D. *See id.* Sections 429.439(A), (C), and (D) each address the relationship between the parent medical center and the satellite clinic. Subsection A specifically addressed "[a] satellite program['s] . . . integrat[ion] with the parent center," including the parent's responsibility for the satellite's regulatory compliance and for "clear lines of supervision and communication." It also states that the satellite must maintain its own records and premises and must abide by the parent's policies. Subsection C requires the parent center to designate a clinical director for the satellite with certain qualifications and responsibilities. Subsection D

requires the satellite program to refer patients to the parent for any services the satellite does not offer. The Second Amended Complaint makes no allegations regarding this parent-satellite relationship. It is entirely silent on the satellite's referrals or compliance with the parent's policies. There are similarly no claims or allegations regarding the parent's designation of a director or dealing with the standards for integration and communication. Thus, none of those standards can form the foundation for a regulatory violation relevant to the claims in this case.

Section 429.439(B) addresses the supervision and in-service training that autonomous satellite programs must provide their staff. As discussed above, the Second Amended Complaint makes no allegation that the Arbour clinic in Lawrence is an autonomous satellite program such that it would be subject to § 429.439(B). It therefore does not raise a plausible claim that Defendant violated § 429.439(B) because there is no allegation - even on information and belief - that the clinic would be subject to it.[2]

[2] And even if this failure to identify the status of the clinic were not enough to render the pleading insufficient, I would decline to hold that alleged failure of Dr. Gaticales and Ms. Fuchu to obtain the required licensure under § 429.424 (which is not a condition of payment) either affects their ability to provide supervision to noncore staff as required by § 429.439(B) (which is expressly a condition of payment) or requires that they be treated as "noncore" staff under that section. The Sixth Circuit has cautioned against such an approach, explaining that it is inappropriate to "weav[e] together isolated phrases from several sections in the complex scheme of Medicare regulations."

Thus, the Second Amended Complaint does not plead any violation of a precondition of payment found in 130 C.M.R. §§ 429.000 *et seq.*, which could give rise to FCA liability.

2. 105 C.M.R. §§ 140.000

The Second Amended Complaint alleges that the Massachusetts Department of Public Health found that United violated various provisions of 105 C.M.R. §§ 140.000. (*See* Second Amended Complaint ¶¶ 187-190.) However, the Second Amended Complaint does not predicate any of its claims on any violation of Title 105, nor have Plaintiffs made any allegation in the Second Amended Complaint or any argument in their brief that Title 105 contains preconditions of payment. Chapter 140 of Title 105 sets out the licensure requirements for health clinics. *See generally*

United States ex rel. Hobbs v. *Medquest Associations, Inc.*, 711 F.3d 707 (6th Cir. 2013). In that case, claims for certain medical tests were payable only if "reasonable and necessary," which required supervision by a physician. *Id.* at 715. The court rejected claims predicated upon the supervising physicians lacking the credentials required of their roles. As the Sixth Circuit explained: "[T]he claims at issue were supervised directly by physicians; for this reason, the claims meet the 'reasonable and necessary' requirement and satisfy the conditions for payment. Additional rules pertaining to the roles and duties of supervising physicians . . . and to additional certifications required for . . . testing procedures are found in separate regulations that do not refer to the 'reasonable and necessary' standard; therefore, interpreting them as relating to the "reasonable and necessary" conditions comes only from a strained reading of the regulatory scheme." *Id.* The logic of *Hobbs*, applied here, suggests that non-compliance with the core-staff qualification requirements of § 429.424 does not trigger a violation of the supervision requirements under § 429.439.

105 C.M.R. §§ 140.000. It does not address the reimbursement process or any prerequisites to reimbursement.

In their brief, Plaintiffs confine their arguments regarding 105 C.M.R. §§ 140.000 to two footnotes. There, Plaintiffs cite to various regulations in Chapter 105 as additional bases for the proposition that violation of supervisory regulations might be material to MassHealth's decision to pay various claims (the primary basis being 130 C.M.R. §§ 429.000, discussed above). This argument is in keeping with Plaintiffs' contention that materiality is the sole consideration in determination whether a regulatory violation amounts to a false claim. As discussed above, however, to render a claim false, an alleged regulatory violation must pertain to a condition of payment, not merely a condition of participation. Nothing in 105 C.M.R. §§ 140.313 (requiring physician staff and responsibility for practice of medicine), 140.520 (describing adequate mental health services standards), or 140.530 (describing staffing requirements for mental health centers) relates to payment in any way. There is nothing to indicate that these regulations act as preconditions of payment, and therefore, submitting claims for reimbursement while in violation of these regulations is not fraudulent and cannot support an FCA claim.

3. 243 C.M.R. § 2.10

The Second Amended Complaint does not mention 243 C.M.R. § 2.10, which sets out the standards governing when "Advanced Practice Nurses" can prescribe medication. However, Plaintiffs raised this regulation for the first time in their opposition to United's motion to dismiss. Plaintiffs argue that Ms. Ortiz, the nurse practitioner who prescribed Trileptal to Ms. Rivera, was not properly supervised and therefore could not prescribe medication without violating 243 C.M.R. § 2.10. Plaintiffs further argue that violations of this regulation could be material to MassHealth's decision to reimburse Arbour. As with the other regulations, discussed above, before Plaintiffs argue materiality, they must show falsity in relation to a claim for payment. They have neither pled nor argued a plausible claim for falsity based on 243 C.M.R. § 2.10.

Title 243 of the Massachusetts Code of Regulations governs the Board of Registration in Medicine. The specific provision Plaintiffs cite sets out the "standards governing the practice of medicine with respect to the supervision of Advanced Practice Nurses (APN) engaged in prescriptive practice." 243 C.M.R. § 2.10(1). Neither the Chapter nor the Title nor the section itself relates to MassHeath reimbursement for clinics providing mental health services. It governs the substantive requirements for Nurse practitioners, but does not govern when MassHealth will

or will not reimburse a clinic. It can therefore neither render a claim for reimbursement false nor support an FCA action.

B. Materiality

Defendant's materiality arguments are, as a practical matter, derivative of its falsity arguments. It argues that none of the regulatory violations Plaintiffs allege could be material to MassHealth's decision to pay United's claims because they are not preconditions to payment. Defendants concede that some courts distinguish between falsity and materiality while "other courts have determined that the absence of a regulation that is a condition of payment means that the element of materiality is not satisfied, but the rationale is the same."

The logic of *Hutcheson* suggests that the determination of materiality is distinct from that regarding whether a regulation is a condition of payment or a condition of participation. There, the First Circuit first determined that the relevant law--the Anti-Kickback Statute--was a condition of payment. *See Hutcheson*, 647 F.3d at 393 ("This makes it abundantly clear that AKS compliance is a precondition of Medicare payment . . ."). Only after reaching that determination does the Court move on to its analysis of materiality. *See id.* at 394-95.

Because I find that the Second Amended Complaint does not sufficiently plead any false statement regarding a precondition

of payment, I do not reach the issue whether any false statement might be material.

C. Pleading with Particularity

Actions under the FCA are subject to Federal Rule of Civil Procedure 9(b), which heightens the pleading requirements in actions that sound in fraud. *See United States ex rel. Gagne* v. *City of Worcester*, 565 F.3d 40, 45 (1st Cir. 2009). Rule 9(b) requires that "[i]n alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake." More specifically, in order to state a claim, a complaint must "specify the time, place, and content of an alleged false representation." *Gagne*, 565 F.3d at 45 (internal quotation marks and citations omitted). In other words, the complaint must "specify the who, what, where, and when of the allegedly false or fraudulent representation." *Alternative Sys. Concepts, Inc.* v. *Synopsis, Inc.*, 374 F.3d 23, 29 (1st Cir. 2004). However, a complaint may satisfy Rule 9(b) even if "some questions remain unanswered, [if] the complaint as a whole is sufficiently particular to pass muster under the FCA." *Rost*, 507 F.3d at 732; *see also City of Worcester*, 565 F.3d at 45.

As discussed above, the claims asserted by the Plaintiffs fail for the substantive reason that they assert, at best, violations of regulations which are not conditions of payment. There is, however, one arguable exception. Plaintiffs have not

completely pled themselves out of a violation of § 429.439(B), which is a condition of payment.

Any FCA claim predicated on a violation of § 429.439(B), however, necessarily must rely on one fundamental assumption: That Arbour is an autonomous clinic. *See supra* Section III(A)(1). The Second Amended Complaint, however, fails to allege this factual element which is necessary to invoke § 429.439(B), which by its own terms only applies only to "an autonomous satellite program." At the motion hearing, Plaintiffs represented that they have no way of knowing whether Arbour is a dependent or autonomous clinic, but this does not absolve them of their responsibilities under Rule 9(b). Whether this is a failure of investigative initiative or not, it is fatal to the claim. In order to survive a motion to dismiss, a complaint must describe "the circumstances constituting fraud or mistake." Fed. R. Civ. P. 9(b). In other words, it must describe the way in which Defendant's statement was fraudulent. In this case, Plaintiffs argue that United committed fraud by submitting claims for reimbursement while knowingly in violation of regulations that were conditions of payment. Arbour could not have violated § 429.439(B) unless it was an autonomous clinic. Therefore, autonomousness is a critical allegation that Plaintiffs must state with particularity. Without this facts, there can be no fraud.

Plaintiff need not prove this facts at this stage. It need not even adduce any evidence, but because "the mere accusation [of fraud] often causes harm," *Rost*, 507 F.3d at 733, Rule 9(b) requires plaintiffs to certify under Rule 11 that they have a good faith basis to make the particular factual allegations demonstrating fraud. This case is no exception. Plaintiffs cannot proceed on this aspect of the Second Amended Complaint without alleging on a good faith basis that Arbour is an autonomous program. If, as represented at the hearing, Plaintiffs do not have the information required to make such allegations in good faith, they simply lack the information to charge Defendant with fraud.

On this third attempt to draft their complaint, Plaintiffs have failed to state with sufficient particularity the factual predicates to Claims I-IV and VIII-XI, and have represented that they cannot do so. I must therefore dismiss these claims for failure to satisfy the requirements of Rule 9(b).

Claims V-VI and XII-XIII also fall far below the pleading bar that Rule 9(b) sets. These counts allege that Arbour submitted unstated, unenumerated claims for reimbursement to MassHealth for unnamed Arbour employees. (*See, e.g.,* Second Amended Complaint ¶ 254.) These allegations admit, on their face, that Plaintiffs cannot state the who, when, or particular content of any potential false claim as Rule 9(b) requires. For

instance, Count VI states "Arbour billed . . . for nurse practitioners who were unsupervised . . . . The specific identity of the names of these nurse practitioners is currently unknown to the Relators but is well known to Arbour." (Second Amended Complaint ¶¶ 265-66.) In *United States ex rel. Karvelas* v. *Melrose-Wakefield Hosp.*, the First Circuit held that "a qui tam relator may not present general allegations in lieu of the details of actual false claims in the hope that such details will emerge through subsequent discovery." 360 F.3d 220, 231 (1st Cir. 2004), *abrogated on other grounds by Allison Engine*, 553 U.S. 662. In *Karvelas*, the plaintiff-relator's claim failed because it did not provide any specific claim dates, identification numbers, or amounts charged to the government. *See id.* at 231; *see also Rost*, 507 F.3d at 732. The same is true in Counts V-VI and XII-XIII in the Second Amended Complaint now before me. They provide no claim numbers, no dates, and no amounts charged to the government. They therefore fail to identify any particular claims that might be false.

The *Karvelas* test does, of course, have some flexibility and if the complaint as a whole states a sufficiently particular claim under the FCA, it will not fail simply because some questions remain unanswered. *See Karvelas*, 360 F.3d at 233 n.17 (explaining that, in the context of the Private Securities Litigation Reform Act, which embodies the standards of Rule 9(b),

certain deficiencies may be excused when the allegations "reinforce each other and suggest reliability of the information reported."). This flexibility does not save Plaintiffs' claims in Counts V-VI and XII-XIII of the Second Amended Complaint. Those counts give no information regarding which clinicians or Nurse Practitioners might have provided unsupervised services, what services they provided, or whether Arbour billed for their services. They have failed to provide "the who, what, where, and when of the allegedly false or fraudulent representation, as required to satisfy Rule 9(b)." *Alternative Sys. Concepts, Inc.* v. *Synopsis, Inc.*, 374 F.3d 23, 29 (1st Cir. 2004).

Although the factual allegations advanced in other parts of the complaint provide some clarity as to Plaintiffs' position, I have already found that, as a matter of law, their other Counts do not state a claim under the FCA. Plaintiffs vague claims are not saved by virtue of being attached to claims that are of greater particularity, but which fail on their merits. I therefore dismiss Counts V-VI and XII-XIII.

D. Public Disclosure Bar

Defendants cursorily raise the public disclosure bar as a potential alternative ground for dismissal. They also argue that because Plaintiffs did not serve the Complaint within five months after the Government declined to intervene in this case and the action was unsealed, the public disclosure bar applies and the

case should be dismissed. *See* 31 U.S.C. § 3730(e)(4); M.G.L. 12 § 5G. However, the public disclosure bar for untimely service is not a jurisdictional bar. Here, I granted Plaintiffs' admittedly belated request for an extension of time to amend and serve the complaint. Because I granted Plaintiffs motion for an extension of time, I find that it would be inappropriate to dismiss the Second Amended Complaint on timeliness grounds and I decline to do so.

V. CONCLUSION

The allegations of this complaint raise serious questions about the quality of care provided to the Plaintiffs' daughter. But the False Claims Act is not the vehicle to explore those questions. The Act and its Massachusetts analog are directed at materially false statements presented to obtain government reimbursement. The Plaintiffs have not, despite three iterations of their complaint, made adequate allegations regarding such statements.

For the foregoing reasons, I GRANT Defendant's Motion to Dismiss the Second Amended Complaint (Dkt. 55).

/s/ Douglas P. Woodlock
DOUGLAS P. WOODLOCK
UNITED STATES DISTRICT