15-7

No. ____

In the Supreme Court of the United States

UNIVERSAL HEALTH SERVICES, INC.,

Petitioner,

v.

UNITED STATES AND COMMONWEALTH OF MASSACHUSETTS EX REL. JULIO ESCOBAR AND CARMEN CORREA,

Respondents.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the First Circuit

PETITION FOR A WRIT OF CERTIORARI

MARK W. PEARLSTEIN
LAURA MCLANE
EVAN D. PANICH
MCDERMOTT WILL & EMERY LLP
28 State Street
Boston, MA 02109
(617) 535-4000

M. MILLER BAKER
Counsel of Record
MCDERMOTT WILL & EMERY LLP
500 North Capitol Street, NW
Washington, DC 20001
(202) 756-8000
mbaker@mwe.com

Counsel for Petitioner

QUESTIONS PRESENTED

The False Claims Act ("FCA") makes it unlawful to present a "false or fraudulent" claim for government reimbursement. 31 U.S.C. § 3729(a)(1)(A). A claim can be "factually false" because, for example, the contractor has not provided the products or services for which reimbursement is sought. Some courts have held that a claim can be "legally false" for purposes of the FCA because the contractor, while providing the products or services for which reimbursement is sought, did not comply with a condition of payment imposed by statute, regulation, or contract. This latter theory of FCA liability is divided into two categories: "express certification" and "implied certification." The viability and scope of the latter theory is at issue here.

Respondents' complaint alleged that petitioner's reimbursement claims were legally false because petitioner's services did not comply with several specific regulatory provisions with which petitioner impliedly certified compliance. The district court dismissed the complaint pursuant to Federal Rules of Civil Procedure 9(b) and 12(b)(6) because none of the regulatory provisions alleged in respondents' complaint, or otherwise cited by respondents in the proceeding, imposed conditions of payment, except one, and respondents did not plausibly allege any violation of that provision.

The First Circuit below reversed, holding that respondents' complaint (1) alleged conduct that violated a regulation neither pled in respondents' complaint nor cited by respondents at any point in the proceedings below, and that (2) compliance with this unpled and uncited regulation was a condition of payment. According to the First Circuit, respondents thus stated a claim

for legal falsity under the FCA. Although the First Circuit has eschewed labels used by other circuits in describing different types of FCA claims, it applied an "implied certification" theory of legal falsity.

The questions presented are:

1. Whether the First Circuit, by *sua sponte* identifying and relying upon a regulatory provision not invoked by respondents at any point in the proceedings below to reverse the district court's dismissal of respondents' complaint, has so far deviated from the adversary system's party presentation rule "so as to call for an exercise of this Court's supervisory power" under this Court's Rule 10(a).

2. Whether the "implied certification" theory of legal falsity under the FCA—applied by the First Circuit below but recently rejected by the Seventh Circuit—is viable.

3. If the "implied certification" theory is viable, whether a government contractor's reimbursement claim can be legally "false" under that theory if the provider failed to comply with a statute, regulation, or contractual provision that does not state that it is a condition of payment, as held by the First, Fourth, and D.C. Circuits; or whether liability for a legally "false" reimbursement claim requires that the statute, regulation, or contractual provision *expressly* state that it is a condition of payment, as held by the Second and Sixth Circuits.

PARTIES TO THE PROCEEDING

Pursuant to Supreme Court Rule 14.1(b), the following list identifies all of the parties appearing here and before the United States Court of Appeals for the First Circuit. The petitioner here, and appellee below, is Universal Health Services, Inc. The respondents here, and appellants below, are the United States of America and the Commonwealth of Massachusetts ex rel. Julio Escobar and Carmen Correa.

CORPORATE DISCLOSURE STATEMENT

Pursuant to Supreme Court Rule 29.6, petitioner states that it has no corporate parent and that no publicly held company owns ten percent or more of petitioner's stock.

TABLE OF CONTENTS

TABLE OF CONTENTS

(continued)

Page

TABLE OF CONTENTS

(continued)

Page

TABLE OF CONTENTS

(continued)

TABLE OF AUTHORITIES

Page(s)

Cases

Statutes

Regulations

Rules

Other Authorities

PETITION FOR A WRIT OF CERTIORARI

Petitioner Universal Health Services, Inc., respectfully petitions this Court for a writ of certiorari to review the decision of the United States Court of Appeals for the First Circuit in this case.

OPINIONS BELOW

The decision of the court of appeals is published as *United States ex rel. Escobar v. Universal Health Services, Inc.*, 780 F.3d 504 (1st Cir. 2015), and is reprinted at Pet. App. 1. The order of the court of appeals denying rehearing is reprinted at Pet. App. 54. The district court's unpublished opinion dismissing respondents' complaint is available on Westlaw at *United States ex rel. Escobar v. Universal Health Services, Inc.*, No. 11-11170-DPW, 2014 WL 1271757 (D. Mass. Mar. 26, 2014), and is reprinted at Pet. App. 25.

JURISDICTIONAL STATEMENT

The United States Court of Appeals for the First Circuit entered its opinion and judgment on March 17, 2015. Petitioner filed a petition for rehearing and for rehearing *en banc* on March 30, 2015, which the court of appeals denied on April 14, 2015. This Court has jurisdiction over this matter pursuant to 28 U.S.C. § 1254(1).

RELEVANT STATUTE AND REGULATIONS

31 U.S.C. § 3729(a)(1) provides in pertinent part:

> [A]ny person who . . . knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval . . . is liable to the United States

> Government for a civil penalty of not less than $5,000 and not more than $10,000, as adjusted by the Federal Civil Penalties Inflation Adjustment Act of 1990[1] . . . , plus 3 times the amount of damages which the Government sustains because of the act of that person.

The relevant provisions of the Code of Massachusetts Regulations are reprinted at Pet. App. 52-62.

INTRODUCTION

This case presents three important questions warranting this Court's review.

The first question is whether the First Circuit so far departed from the "ordinary and usual course" of judicial decision-making as to warrant the exercise of this Court's supervisory authority under Rule 10(a). In the decision below, the First Circuit *sua sponte* identified a regulatory provision never previously cited or invoked by respondents, and relied upon that provision to reverse the district court's dismissal of respondent's complaint. The First Circuit's departure from the adversary system's "party presentation rule" warrants summary reversal on that basis alone.

The second and third questions presented concern an issue that the lower courts have repeatedly addressed resulting in inconsistent outcomes for more than two decades: the viability and scope of "implied certification" claims—*i.e.*, claims based upon a statuto-

---

[1] The Federal Civil Penalties Inflation Adjustment Act of 1990 has adjusted the civil penalties to not less than $5,500 and not more than $11,000. 28 C.F.R. § 85.3(a)(9).

ry, regulatory, or contractual violation—under the FCA.

The disagreement among the circuits exists at two different levels. As an initial matter, the circuits disagree on whether "implied certification" claims may be brought at all under the FCA. The Seventh Circuit recently answered this question with a resounding "no." *United States v. Sanford-Brown, Ltd.*, No. 14-2506, 2015 WL 3541422, at *12 (7th Cir. June 8, 2015) ("Although a number of other circuits have adopted the so-called doctrine of implied false certification . . . we decline to join them. . . ."). The Seventh Circuit held that the implied certification theory of liability advocated by the relator and the government "lack[ed] a discerning limiting principle." *Id.* It further reasoned that the FCA "is simply not the proper mechanism" to enforce compliance with statutes, regulations, and contractual provisions applicable to a contractor by virtue of that contractor's agreement to participate in an agency program, and that compliance with an agency's requirements is best left to the agency to adjudicate. *Id.*

Other circuits (including the First Circuit, as in this case) allow FCA claims to go forward based on violations of statutes, regulations, and contractual provisions, even where the services for which the contractor sought reimbursement were provided, and even where the contractor, in submitting a claim for reimbursement, did not expressly certify compliance with the statute, regulation, or contractual provision. These circuits recognize the implied certification theory and in doing so have opened the door to potentially limitless liability under the FCA, far beyond its intended purposes and scope. The circuits have also engineered dramatically divergent interpretations of the "implied

certification" theory, leading to inconsistent results across jurisdictions.

Indeed, the circuits that recognize the implied certification theory apply the theory in inconsistent ways. While every such circuit requires that compliance with the statute, regulation, or provision allegedly transgressed be a condition of payment by the government payor, these circuits differ on whether a condition of payment must be expressly identified as such, or whether a statute, regulation, or contractual provision can be a "condition of payment" even if it does not state that payment is conditioned on compliance.

The Second and Sixth Circuits fall into the former category, recognizing that a contractor impliedly certifies compliance with a statute, regulation, or contractual provision for purposes of FCA liability only if the government expressly conditions payment on compliance; the legal obligation in question must be explicitly designated a condition of payment. *Mikes v. Strauss*, 274 F.3d 687, 700-02 (2d Cir. 2001); *Chesbrough v. VPA, P.C.*, 655 F.3d 461, 468 (6th Cir. 2011).

While the First, Fourth, and D.C. Circuits recognize the condition of payment requirement, these circuits do not require a legal obligation to be expressly and clearly identified as a condition of payment; instead, courts in these circuits may find "implied conditions of payment" without any basis in the text of the relevant statute, regulation, or contract. *U.S. ex rel. Hutcheson v. Blackstone*, 647 F.3d 377, 386-88 (1st Cir. 2011); Pet. App. 13 (following *Hutcheson*); *United States v. Triple Canopy, Inc.*, 775 F.3d 628, 636 (4th Cir. 2015); *United States v. Sci. Apps. Int'l Corp.*, 626 F.3d 1257, 1269 (D.C. Cir. 2010) [hereinafter

SAIC]. None of these circuits has articulated a clear standard for determining when a statute, regulation, or contractual provision is a condition of payment in the absence of express language.

The First Circuit's decision below cemented the hopeless divide among the circuits in two ways. As an initial matter, the decision below is directly at odds with the Seventh Circuit's recent rejection of the implied certification theory of FCA liability. While the First Circuit purports to reject the label "implied certification," there is no uncertainty about the fact that it allowed an FCA claim to proceed based upon petitioner's alleged noncompliance with a state Medicaid regulation.[2]

Moreover, the First Circuit's decision is at odds with the Second and Sixth Circuits, in that it allowed an implied certification claim to proceed in the absence of an express condition of payment: the Massachusetts Medicaid agency, MassHealth, has not expressly stated that compliance with the regulation at issue, which sets forth a nonexhaustive list of job responsibilities for a mental health center's clinical director, is a condition of payment. By nonetheless holding that the regulation is a condition of payment, the First Circuit has converted the FCA into the bluntest of instruments that goes far beyond Congress's intent to create a means to recover damages caused by fraud against the government.

If this Court does not summarily reverse or otherwise grant certiorari on the first question presented,

---

[2] Respondents never alleged that petitioner expressly certified compliance with that regulation.

the Court should at least grant certiorari on the second and third questions presented to resolve the two splits among the circuits implicated here. First, it should, consistent with the Seventh Circuit, reject the implied certification theory of FCA liability because it is inconsistent with the statute's purpose. Second, even if this Court recognizes the implied certification theory or declines to address that issue, it should, at a minimum, require that in an implied certification case, the underlying statute, regulation, or contract must expressly state that the government payor conditions payment on compliance.

STATEMENT

A. Factual Background

Petitioner's subsidiary operates a mental health clinic in Lawrence, Massachusetts (the "Lawrence clinic"), which receives federal and state reimbursement through the state Medicaid program, MassHealth. Pet. App. 3-4. The Lawrence clinic is a "satellite" of a parent center located in Malden, Massachusetts. Pet. App. 3.

Respondents Julio Escobar and Carmen Correa are the step-father and mother of Yarushka Rivera, a patient at the clinic who died of a seizure in 2009. Pet. App. 26. Respondents thereafter filed several complaints with state agencies concerning alleged deficiencies in the quality of service provided at the Lawrence clinic. Pet. App. 7-8.

B. Proceedings Below

1. Respondents brought this action in 2011 as relators under the *qui tam* provisions of the False Claims Act, 31 U.S.C. § 3730(b), in the United States District

Court for the District of Massachusetts.[3] Both the United States and Commonwealth of Massachusetts declined to intervene.

Respondents then filed a first amended complaint, which petitioners moved to dismiss. After briefing and argument, the district court granted respondents leave to file a second amended complaint "on the understanding that Plaintiffs must be willing to rise or fall on their new [c]omplaint." Pet. App. 32.

In their second amended complaint, respondents alleged that: (1) named and unnamed caregivers at the Lawrence clinic were not properly supervised in violation of MassHealth regulations; and (2) the Lawrence clinic violated the staff composition requirements contained in those regulations because it did not employ a board certified or board eligible psychiatrist and a licensed psychologist. Pet. App. 29. Respondents alleged that petitioner violated the following MassHealth regulations: 130 Mass. Code Regs. §§ 429.408, 429.422, 429.423(D), 429.424(A), 429.424(B), 429.424(E), 429.437, 429.439. Second Amended Complaint, Dist. Ct. Dkt. No. 50. Respondents alleged that compliance with each of these regulations is a condition of payment by MassHealth.

Petitioner then moved to dismiss the second amended complaint pursuant to Federal Rules of Civil Procedure 9(b) and 12(b)(6), which the district court

---

[3] Respondents also brought identical claims under the *qui tam* provisions of Massachusetts False Claims Act, Mass. Gen. Laws ch. 12, § 5C(2). Because the federal False Claims Act and its Massachusetts counterpart are very similar, "the state statute may be construed consistently with the federal act." Pet. App. 17 n.13 (citation and internal quotation marks omitted).

granted. Pet. App. 53. Of the regulations identified by respondents in the second amended complaint, as well as four additional regulations cited by respondents in their briefing, *see* Pet. App. 39, the district court concluded that only one, 130 Mass. Code Regs. § 429.439, was a condition of payment.[4]

Respondents alleged that under section 429.439 "some supervision requirements are pre-conditions to payment," Pet. App. 38 (citing Second Amended Complaint ¶ 12), but the district court concluded that respondents had not plausibly alleged that the petitioner had violated that provision because none of the supervisory "standards [contained in section 429.439] can form the foundation for a regulatory violation relevant to the claims in this case." Pet. App. 44.

2. On appeal, the First Circuit did not reject the district court's conclusion that, except for section 429.439, none of the regulatory provisions invoked by respondents in their second amended complaint and briefing imposed compliance as a condition of payment. Pet. App. 15. Nor did the First Circuit disagree with the district court's conclusion that respondents did not allege any plausible violation of section 429.439's supervisory standards.

Instead, the First Circuit faulted the district court for "overlook[ing]," Pet. App. 16, another regulation that respondents *never* invoked (either in the district court or on appeal): 130 Mass. Code Regs. § 429.423(B)(2), which is referenced in section 429.439.

---

[4] Section 429.439 provides "[s]ervices provided by a satellite program are reimbursable only if the program meets the standards described below." 130 Mass. Code Regs. § 429.439.

Specifically, section 429.439(C) provides that"[t]he clinical director must be employed on a full-time basis and meet all of the *requirements* in 130 [Mass. Code Regs. §] 429.423(B)." 130 Mass. Code Regs. § 429.439(C) (emphasis added).

Section 429.423(B) contains two paragraphs. Paragraph (1) provides the "requirements" that a satellite facility's clinical director must meet:

> The clinical director must be licensed, certified, or registered to practice in one of the core disciplines listed in 130 [Mass. Code Regs. §] 429.424, and must have had at least five years of full time, supervised clinical experience subsequent to obtaining a master's degree, two years of which must have been in an administrative capacity. The clinical director must be employed on a full-time basis.

130 Mass. Code Regs. § 429.423(B)(1).

Respondents did not allege, and the First Circuit did not conclude, that the clinical director of the Lawrence clinic failed to meet any of the *requirements* identified in paragraph (1). Instead, the court of appeals relied on paragraph (2), which provides that the "specific *responsibilities* of the clinical director include"

> (a) selection of clinical staff and maintenance of a complete staffing schedule;
>
> (b) establishment of job descriptions and assignment of staff;
>
> (c) overall supervision of staff performance;
>
> (d) accountability for adequacy and appropriateness of patient care;
>
> (e) in conjunction with the medical director, accountability for employing adequate psychiatric

staff to meet the psychopharmalogical needs of clients;

(f) establishment of policies and procedures for patient care;

(g) program evaluation;

(h) provision of some direct patient care in circumstances where the clinical director is one of the three minimum full-time equivalent staff members of the center;

(i) development of in service training for professional staff; and

(j) establishment of a quality management program.

130 Mass. Code Regs. § 429.423(B)(2) (emphasis added).

The First Circuit held that (1) because section 429.439 conditions payment on compliance with "the standards described below," and (2) because section 429.439(C) states that a clinical director must satisfy "all of the *requirements* in [section] 429.423(B)," then, by extension, (3) every part of section 429.423(B) is a material condition of payment. Pet. App. 16 (emphasis added). Thus, as section 429.423(B)(2)(c) states that a clinic director is responsible for "overall supervision of staff performance," then "[i]nsofar as [respondents] have alleged noncompliance with regulations pertaining to supervision, they have provided sufficient allegations of falsity to survive a motion to dismiss." Pet. App. 16.

The First Circuit reached this conclusion even though nothing in section 429.423 conditions payment on the nonexhaustive list of "specific responsibilities" of

the clinical director listed in subsection (B)(2). (Instead, subsection (B)(1)—not (B)(2)—lists the "requirements" of the clinical director contemplated by section 429.439(C).) Moreover, respondents did not generally allege violation of "regulations pertaining to supervision." Instead, respondents alleged violations of specific regulations, including section 429.439, but *not* section 429.423(B).

The First Circuit further concluded that respondents plausibly alleged that the Lawrence clinical director failed to employ "adequate" psychiatric staff, *see* 130 Mass. Code Regs. § 429.423(B)(2)(e), by alleging that the Lawrence clinic's psychiatrist was not board certified, Pet. App. 20-22. Although the regulation does not define "adequate," the court concluded that respondents sufficiently alleged a violation of this regulation. The court reached this conclusion by relying on another, unrelated regulation issued by a different agency, the Massachusetts Department of Public Health ("DPH"): 105 Mass. Code Regs. § 140.530, which requires mental health centers to have a board certified psychiatrist on staff. But this DPH regulation is tethered to neither section 429.423(B)(2) nor section 429.439. In addition, no statute, regulation, or contractual provision suggests that compliance with section 140.530 is a condition of MassHealth reimbursement.

Because respondents did not argue at any point during the proceedings before the district court or the First Circuit that petitioner had either failed to comply with section 429.423(B)(2) or that this regulation was a condition of payment, petitioner moved for rehearing on this basis. The First Circuit denied rehearing.

REASONS FOR GRANTING THE PETITION

I. The First Circuit's Departure from the Party Presentation Rule Warrants Exercise of This Court's Supervisory Authority

"In our adversary system, in both civil and criminal cases, in the first instance and on appeal, we follow the principle of party presentation." *Greenlaw v. United States*, 554 U.S. 237, 243 (2008). Under that principle, courts "rely on the parties to frame the issues for decision and assign to courts the role of neutral arbiter of matters the parties present." *Id.* Accordingly, "the legal parameters of a given dispute are framed by the positions advanced by the adversaries, and may not be expanded *sua sponte* by the [court]." *GJR Invs., Inc. v. Cnty. of Escambia, Fla.*, 132 F.3d 1359, 1369 (11th Cir. 1998) (quoting *Doubleday & Co. v. Curtis*, 763 F.2d 495, 502 (2d Cir. 1985)) (internal quotation marks omitted), *overruled on other grounds as recognized in Randall v. Scott*, 610 F.3d 701, 709 (11th Cir. 2010).

Here, the First Circuit *sua sponte* expanded the legal parameters beyond respondents' second amended complaint by first identifying, and then relying upon, 130 Mass. Code Regs. § 429.423(B), a regulatory provision never once invoked by respondents in their complaint, briefing, or oral arguments in the proceedings below. The First Circuit's "depart[ure] from the ordinary and usual course of judicial proceedings," Sup. Ct. R. 10(a), is all the more stark given the issue before it: whether respondents' second amended complaint alleged with sufficient "particularity the circumstances constituting fraud." Fed. R. Civ. P. 9(b).

In this context of alleged "legal falsity" under the FCA, respondents were required to allege, *with particu-*

larity, the regulatory provisions allegedly violated by petitioners for which compliance is a condition of payment. *See Schindler Elevator Corp. v. U.S. ex rel. Kirk*, 131 S. Ct. 1885, 1898 (2011) (recognizing that the particularity requirement applies to FCA claims); *U.S. ex rel. Ge v. Takeda Pharm. Co.*, 737 F.3d 116, 125 (1st Cir. 2013) (dismissing FCA claims and holding that "courts should not be asked to guess the contents of a theory of liability"), *cert. denied*, 135 S. Ct. 53 (2014). The district court determined that none of the regulatory provisions actually alleged or otherwise cited by respondents imposed compliance as a condition of payment, save one: 130 Mass. Code Regs. § 429.439. Pet. App. 16, 43. As to that regulation's standards, the district court concluded that respondents did not plausibly allege any violation. Pet. App. 44.

The First Circuit did not disagree with the district court's analysis, insofar as it went. Rather than affirm the district court, however, the First Circuit *sua sponte* identified 130 Mass. Code Regs. § 429.423(B) as imposing a condition of reimbursement by operation of section 429.439(C). Pet. App. 16. The court held that respondents' second amended complaint sufficiently alleged a violation of the "overall supervision of staff performance" job function of a clinical director set forth in section 429.423(B)(2), Pet. App. 16,[5] even though respondents never alleged a violation of sec-

[5] Specifically, the First Circuit referenced section 429.423(B) as "mak[ing] plain that one of [the clinical director's] duties is ensuring appropriate supervision." Pet. App. 16. As discussed above, paragraph (1) of section 429.423(B) sets forth the requirements of a clinical director, whereas paragraph (2) sets forth a nonexhaustive list of a clinical director's job functions, including "overall supervision of staff performance."

tion 429.423(B)(2) in their second amended complaint or otherwise cited that provision at any time in the proceedings below.

Because the First Circuit's decision below "departed from the ordinary and usual course of judicial proceedings," Sup. Ct. R. 10(a), by violating the principle that courts "normally decide only questions *presented by the parties*," *Greenlaw*, 554 U.S. at 244 (emphasis added) (citation and internal quotation marks omitted), this Court should exercise its supervisory authority and grant certiorari on the first question presented. Indeed, the First Circuit's departure from settled norms of judicial decision-making is so stark as to make summary reversal on this ground appropriate.[6]

II. The First Circuit's Decision Conflicts with the Seventh Circuit's Recent Rejection of the Implied Certification Theory of Liability

On June 8, 2015, the Seventh Circuit issued a decision in which it definitively rejected the relator's and the government's reliance on the implied certification theory of liability. *United States v. Sanford-Brown, Ltd.*, No. 14-2506, 2015 WL 3541422, at *12 (7th Cir. June 8, 2015). In *Sanford-Brown*, the relator argued that Sanford-Brown college violated the FCA when it received federal subsidies from the U.S. Department of Education while allegedly in violation of a variety of federal regulations. *Id.* at *2. The relator contended that such regulatory violations gave rise to false claims

---

[6] If this Court declines to either summarily reverse or grant plenary review of the first question presented, petitioners waive that non-jurisdictional issue and urge this Court to grant certiorari limited to the second and third questions presented.

by virtue of a program participation agreement ("PPA") into which the college was required to enter into in order to take part in the subsidy program. *Id.* The PPA required the college "to abide by a panoply of statutory, regulatory, and contractual requirements." *Id.*

The Seventh Circuit affirmed the district court's grant of summary judgment in favor of the college. *Id.* at *1. In analyzing the relator's theory of FCA liability under 31 U.S.C. § 3729(a)(1)(A), the Seventh Circuit held,

> [W]e conclude that it would be equally unreasonable for us to hold that an institution's continued compliance with the thousands of pages of federal statutes and regulations incorporated by reference into the PPA are conditions of payment for purposes of liability under the FCA. *Although a number of other circuits have adopted this so-called doctrine of implied false certification, we decline to join them* and instead join the Fifth Circuit.[7]

Id. at *12 (emphasis added).[8] The court further noted that "before today, this doctrine was 'unsettled' in this

---

[7] The Fifth Circuit has not explicitly rejected the implied certification theory, but has not adopted it either. *U.S. ex rel. Steury v. Cardinal Health, Inc.* (*Steury II*), 735 F.3d 202, 207 (5th Cir. 2013) (per curiam) (affirming dismissal and noting that "this court has not definitively ruled on the cognizability of implied false certification claims . . . ."); *U.S. ex rel. Steury v. Cardinal Health, Inc.* (*Steury I*), 625 F.3d 262, 268 (5th Cir. 2010) (affirming dismissal and noting that "[t]his Court has not yet recognized the implied-certification theory. . . . The FCA is not a general 'enforcement device' for federal statutes, regulations, and contracts." (citation omitted)).

[8] The "implied certification" theory has been questioned by leading commentators. *See* John T. Boese, *Civil False Claims and Qui*

circuit." *Id.* at *12 n.7 (citing *U.S. ex rel. Grenadyor v. Ukranian Village Pharmacy, Inc.*, 772 F.3d 1102, 1106 (7th Cir. 2014) (further citation omitted)). In rejecting "implied certification" under the FCA, the court reasoned that a violation of a regulation applicable to a government contractor "is for the agency—not the court—to evaluate and adjudicate." *Id.* at *12. Indeed,

> [l]est there be any doubt about the U.S. Department of Education's ability to enforce the PPA through administrative mechanisms here, its regulations are clear that at all times it possessed the authority up to and including the power to terminate SBC from its subsidy program. However, in this case, the subsidizing agency—as well as other federal agencies—have already examined SBC multiple times over and concluded that neither administrative penalties nor termination was warranted.

Id. (citations omitted).

The Seventh Circuit's reasoning for rejecting "implied certification" was sound, and stands in stark contrast to the result in the instant case. MassHealth—

Tam Actions § 2.03[G], at 2-190 (4th ed. 2011) ("There are a number of critical flaws in the [implied certification] theory, both as a matter of purely legal theory and also as it has been applied in actual cases. Most important, allowing liability to be imposed because of false implied certifications has the practical effect of eliminating the government's burden of proving that a defendant knowingly submitted a false claim to the government. Instead, such cases are based on the allegation that a defendant knowingly and falsely implied that it never fell out of compliance with certain laws, regulations, or contract terms. This remarkable leap in reasoning [is] one that is contrary to the clear language of the statute . . . .").

the payor here[9]—has numerous remedies available to it to address violations of its regulations, ranging from administrative fines to suspension from the program. 130 Mass. Code Regs. §§ 450.238-.249. Respondents have not alleged that MassHealth ever availed itself of any such remedies. Application of the implied certification theory of liability, particularly in circumstances such as this, usurps the agency's role in evaluating and adjudicating violations of its regulations.

Although the First Circuit below purported to eschew the "distinctions . . . between implied and express certification theories," Pet. App. 12, it effectively applied the "implied certification" theory rejected by the Seventh Circuit, as it did not find—and the record would not support—a determination that respondents alleged that petitioner expressly certified compliance with the applicable MassHealth regulations. Instead, the theory of liability the First Circuit endorsed is that, regardless of what its claims said, petitioner violated the FCA by submitting claims for reimbursement while allegedly in violation of a regulation. Accordingly, despite its rejection of "labels," the First Circuit applied the implied certification theory of liability.

This Court should grant certiorari, adopt the Seventh Circuit's reasoning, and reverse the First Circuit's decision in this matter because petitioner never expressly certified compliance with section 429.423(B)(2) in connection with its claims for reimbursement.

---

[9] MassHealth's use of federal Medicaid dollars to pay petitioner's reimbursement claims implicates potential FCA liability. *See* 42 U.S.C. § 1396b (providing for federal funding to state Medicaid programs); *see also* Second Amended Complaint, Dist. Ct. Dkt. No. 50, ¶ 1.

III. The Circuits Are Intractably Divided on the Scope of the Implied Certification Theory of FCA Liability

In circuits that recognize implied certification FCA claims, courts require that the underlying regulation (or statute or contractual provision) be a condition of payment by the government payor. The condition of payment requirement "ultimately has to do with whether it is fair to find a false certification or false claim for payment in the first place." *U.S. ex rel. Steury v. Cardinal Health, Inc.* (*Steury I*), 625 F.3d 262, 269 (5th Cir. 2010). This is because a claim for payment can only conceivably be "false" where it seeks money or property "to which a defendant is not entitled." *United States v. Southland Mgmt. Corp.*, 326 F.3d 669, 674-75 (5th Cir. 2003) (en banc).

Despite universal recognition of the condition of payment requirement, the circuits disagree about whether a condition of payment must be expressly identified as such.

A. There Is a Circuit Split Regarding Whether a Condition of Payment Must Be Expressly Identified

The Second and Sixth Circuits recognize that a contractor impliedly certifies compliance with a statute, regulation, or contractual provision for purposes of FCA "falsity" only if the government expressly conditions payment on compliance; the legal obligation in question must be explicitly designated a condition of payment. *Mikes v. Strauss*, 274 F.3d 687, 702 (2d Cir. 2001) (rejecting implied certification claim where statute invoked by relator "does not *expressly* condition payment on compliance with its terms" (emphasis add-

ed)); *Chesbrough v. VPA, P.C.*, 655 F.3d 461, 468 (6th Cir. 2011) (rejecting implied certification claim where the relator did not allege that the defendant "was *expressly* required to comply with those standards as a prerequisite to payment of claims (emphasis added)).

By contrast, the First, Fourth, and D.C. Circuits do not require a condition of payment to be expressly and clearly identified. Instead, courts in these circuits may find "implied conditions of payment" without any basis in the text of the relevant statute, regulation, or contract. *See U.S. ex rel. Hutcheson v. Blackstone*, 647 F.3d 377, 386-88 (1st Cir. 2011) (rejecting a "categorical rule" that "a claim can be false or fraudulent for impliedly misrepresenting compliance with a legal condition of payment if that condition is found expressly stated in the relevant statute or regulations" and acknowledging disagreement with the Second Circuit in *Mikes* (citation and internal quotation marks omitted)); Pet. App. 13 & n.11 (holding that "[p]reconditions of payment . . . need not be 'expressly designated'" and acknowledging disagreement with the Second Circuit in *Mikes* (quoting *Hutcheson*, 647 F.3d at 387)); *United States v. Triple Canopy, Inc.*, 775 F.3d 628, 636 (4th Cir. 2015) (holding that an FCA plaintiff pleads a false claim when it alleges that a defendant "withheld information about its noncompliance with material contractual requirements" and evaluating whether the plaintiff met this standard by applying "common sense"); *SAIC*, 626 F.3d 1257, 1269-70 (D.C. Cir. 2010) (holding that "[t]he existence of express contractual language specifically linking compliance to eligibility for payment may well constitute dispositive evidence of materiality, but it is not . . . a necessary condition," and noting disagreement with the Second Circuit in *Mikes*).

Moreover, none of these circuits has articulated a clear standard for determining when a statute, regulation, or contractual provision is a condition of payment in the absence of express language.

As the First Circuit below expressly acknowledged, *see* Pet. App. 13 n.11, its decision stands in conflict with the rule followed in the Second and Sixth Circuits. The First Circuit found a condition of payment in section 429.423(B)(2) even though MassHealth has not expressly identified this regulation as a condition of payment. For the reasons discussed above and below, the Second and Sixth Circuits would have affirmed, rather than reversed, the district court in this case.

B. Requiring Express Conditions of Payment Is Consistent with the Purpose of the Statute, Principles of Fair Notice, and Judicial Economy

1. *The FCA Is Not a Blunt Instrument to Enforce Compliance with Every Legal Obligation of a Government Contractor*

Limiting the implied certification theory to cases where the plaintiff has pled a violation of an express condition of payment appropriately limits the FCA's scope in a manner consistent with the statute's purpose. In passing the FCA, Congress intended to provide a means to combat fraud on the government, which causes the government to lose money:

> PURPOSE OF THE BILL. The False Claims Act is the principal litigative tool employed by the Government to *recover losses sustained as a result of fraud and corruption.*

S. Rep. No. 96-615, at 1 (1980) (emphasis added); *see also Mikes*, 274 F.3d at 699 ("[T]he False Claims Act was not designed for use as a blunt instrument to enforce compliance with all medical regulations—but rather only those regulations that are a precondition to payment.").

A contractor does not defraud the government where it is unclear what the contractor is certifying when it submits a claim for payment. *See Allison Engine Co. v. U.S. ex rel. Sanders*, 553 U.S. 662, 671 (2008) (noting that the FCA "demands . . . that the defendant made a false record or statement for the purpose of getting a false or fraudulent claim paid or approved by the Government"). Indeed, the notion that a contractor commits fraud on the government when it seeks payment while committing a minor infraction of a regulation that is not identified as a condition of payment, but which may later be deemed as such by a court, is untenable. Requiring that conditions of payment be expressly and clearly stated ensures that the district courts can consistently determine when defendants have actually submitted "false" claims.

This consistency is crucial to limiting the FCA to its intended role in combating fraudulent claims, and preventing it from becoming a punitive sanction for use against minor regulatory or contractual violations.

2. *Requiring Express Conditions of Payment Provides Notice to Government Contractors of What Conduct Gives Rise to FCA Liability*

Properly limiting the implied certification theory to cases in which plaintiffs allege violations of express conditions of payment will ameliorate the burdens of

compliance for contractors, by providing notice of what conduct will expose them to liability under the FCA. This Court has stressed the importance of providing fair notice of conduct that will result in a punitive sanction. *BMW of N. Am., Inc. v. Gore*, 517 U.S. 559, 574 (1996) ("Elementary notions of fairness enshrined in our constitutional jurisprudence dictate that a person receive fair notice not only of the conduct that will subject him to punishment, but also of the severity of the penalty that a State may impose.").

Particularly in the health care context, government contractors operate in a "complex" web of regulations. *U.S. ex rel. Hobbs v. MedQuest Assocs., Inc.*, 711 F.3d 707, 715 (6th Cir. 2013). As the law of implied certification under the FCA currently stands, whether a statute, regulation, or contractual provision is a condition of payment such that it can give rise to FCA liability is very much dependent on the circuit in which the case is brought. In the circuits that allow claims to proceed based on conditions of payment that are not express, there is no clear, much less uniform, standard used for identifying whether a legal obligation is a purported "implied" condition of payment. *See, e.g.*, *Triple Canopy*, 775 F.3d at 636-37 (holding that an FCA plaintiff pleads a false claim when it alleges that a defendant "withheld information about its noncompliance with material contractual requirements" and evaluating whether the plaintiff met this standard by applying "common sense").

It is no answer that notice exists by virtue of the underlying legal obligation. It is one thing to say that a contractor is required to comply with, for example, applicable regulations and will be subject to administrative sanctions for regulatory violations. It is another

thing entirely to say that such regulations may also give rise to treble damages and penalties under the FCA. This latter result should be occasioned only when clear and fair notice has been given. That notice is accomplished, as the Second and Sixth Circuits have held, through requiring that a regulatory (or statutory or contractual) condition of payment be expressly identified.

Indeed, allowing FCA claims to proceed based on unidentified "conditions of payment" leaves the question of whether a claim is false to a wholly subjective determination that is both *ad hoc* and *post hoc*. A contractor's expectation about what legal obligations are conditions of payment might reasonably be at odds with a court's conclusion about exactly what is "implied." Moreover, determinations about whether a particular statute, regulation, or contractual obligation is a condition of payment may be different in different courts. Exposing providers and contractors to punitive FCA liability in the face of such inconsistencies is improper and unfair. *See Mikes*, 274 F.3d at 700 ("Liability under the Act may properly be found therefore when a defendant submits a claim for reimbursement while knowing . . . that payment expressly is precluded because of some noncompliance by the defendant.").

3. *Clarifying the Pleading Burden for FCA Plaintiffs Will Curtail Meritless Suits*

Given that courts that allow implied certification FCA claims universally recognize the condition of payment requirement (but differ on how to analyze it), requiring that conditions of payment be express will curtail meritless FCA claims. In an implied certification case, courts are called upon to evaluate whether a legal

obligation is a condition of payment at the pleading stage, in order to determine whether a plaintiff has alleged that a claim for payment was "false." *Steury I*, 625 F.3d at 269 (noting that the condition of payment requirement "ultimately has to do with whether it is fair to find a false certification or false claim for payment in the first place"). In the absence of a clear standard to make this determination, some courts have effectively abdicated their role in assessing whether falsity has been pled, instead stating that they can curtail meritless suits at the pleading stage by "strict enforcement of the Act's materiality and scienter requirements." *SAIC*, 626 F.3d at 1270.

This is not an adequate answer: materiality and scienter are elements of an FCA claim that are separate and independent of falsity. *Sanford-Brown*, 2015 WL 3541422, at *12 n.6 (observing that "[w]hether a violation is material or not has no impact on" whether a claim is false).[10]

---

[10] Moreover, while materiality and scienter may be subject to resolution on the pleadings in some cases, in many cases courts find that, because these elements are highly dependent on the facts, they often cannot be dealt with on the pleadings. *See U.S. ex rel. Loughren v. Unum Grp.*, 613 F.3d 300, 308 (1st Cir. 2010) (noting that "materiality in the FCA context involves a factual determination of the weight that the decisionmaker would have given particular information"); *U.S. ex rel. Farmer v. City of Hous.*, 523 F.3d 333, 346 (5th Cir. 2008) (Jones, J., concurring in part) (noting that "the scienter finding in this [an FCA] case turns on a morass of factual distinctions"); *see also Page v. Postmaster Gen. & Chief Exec. Officer of U.S. Postal Serv.*, 493 F. App'x 994, 995 (11th Cir. 2012) ("In adjudicating a motion to dismiss, the district court may not resolve factual disputes." (citations omitted)).

It is improper for courts to relieve an FCA plaintiff from pleading falsity simply because the court lacks a coherent standard to address the issue. Allowing FCA plaintiffs to proceed to discovery based upon allegations that the defendant violated a legal obligation without any meaningful analysis as to whether payment by the government was conditioned upon compliance with that obligation will permit plaintiffs to exercise the significant leverage of the discovery process to obtain settlements based upon the avoidance of legal costs. *Cf. Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 558 (2007) (recognizing the massive costs of discovery and that "the threat of discovery expense will push cost-conscious defendants to settle even anemic cases before reaching those proceedings"); *Associated Gen. Contractors of Cal., Inc. v. Carpenters*, 459 U.S. 519, 528 n.17 (1983) (noting that "a district court must retain the power to insist upon some specificity in pleading before allowing a potentially massive factual controversy to proceed"). Requiring that conditions of payment be expressly stated will ensure that courts engage in a proper analysis of falsity at the pleading stage to weed out meritless claims.

C. The Decision Below Is Erroneous under the Legal Standard Applied by the Second and Sixth Circuits

Under the rule followed by the Second and Sixth Circuits, a contractor impliedly certifies compliance with a statute, regulation, or contractual provision for purposes of FCA "falsity" only if the government expressly conditions payment on compliance. *See Mikes*, 274 F.3d at 702; *Chesbrough*, 655 F.3d at 468. Under that standard, the First Circuit would have affirmed,

rather than reversed, the district court's dismissal of respondents' second amended complaint.

The First Circuit held that "insofar as Relators have alleged noncompliance with regulations pertaining to supervision, they have provided sufficient allegations of falsity to survive a motion to dismiss." Pet. App. 16. This was because 130 Mass. Code Regs. § 429.423(B)(2) "delineates the clinical director's responsibilities, including, *inter alia*, "overall supervision of staff performance." *Id.*[11]

According to the First Circuit, compliance with section 429.423(B)(2) was a condition of payment because the preamble to section 429.439 states that "[s]ervices provided by a satellite program are reimbursable only if the program meets the standards described below." Subsection (C) of section 429.439 in turn provides that a clinical director must "meet all of the requirements in 130 [Mass. Code Regs. §] 429.423(B)."

The only "requirements" in section 429.423(B) are contained in paragraph (1), which states that "[t]he clinical director *must* be licensed," "*must* have had at least five years of full-time supervised clinical experience," and "*must* be employed on a full-time basis." 130 Mass. Code Regs. § 429.423(B)(1) (emphasis added). These are clearly "requirements," as they describe things that the clinic director "must" or "shall" do. *See, e.g.*, *Flora v. United States*, 357 U.S. 63, 68 (1958) ("If the compliance with this condition . . . *requires* the party aggrieved to pay the money, he *must* do it." (empha-

[11] As noted above in Part I, respondents never invoked 130 Mass. Code Regs. § 429.423(B) at any point in the district court or First Circuit proceedings below.

sis added)). Respondents did not allege, and the First Circuit did not hold, that petitioner violated any of these requirements, which are expressly made a condition of payment by operation of section 429.439(C).

The First Circuit relied instead on the "responsibilities" in section 429.423(B)(2). The court's reliance is misplaced because the "condition of payment" language in section 429.439, on which the First Circuit's decision hinges, does not expressly extend to section 429.423(B)(2). Rather, section 429.423(B)(2) enumerates a nonexhaustive list of a clinic director's job functions. Unlike subsection (B)(1), the enumerated "responsibilities" in subsection (B)(2) do not state that the clinic director "must" or is "required" to do anything. Instead, this subsection simply provides a job description for a satellite facility's clinical director, including (but not defining) "overall supervision" of staff. These "responsibilities," including "overall supervision" are not the "requirements" referenced in section 429.439(C), and hence are not expressly made a condition of payment.

In sum, while section 429.439—compliance with which is a condition of payment—requires that a "clinical director must be employed on a full-time basis and meet all of the requirements in [section] 429.423(B)," such requirements are contained in section 429.423(B)(1). The nonexhaustive list of "responsibilities" listed in section 429.423(B)(2) are not the "requirements" contemplated by section 429.439, and section 429.423(B)(2) does not otherwise explicitly state that it is a condition of payment by MassHealth.

Accordingly, by concluding that subsection (B)(2) of section 429.423 is a condition of payment, the First

Circuit determined that this subsection was an *implied* condition of payment. Under the standard followed by the Second and Sixth Circuits, this is not sufficient to state a violation of the FCA. Indeed, this approach would lead to potentially absurd results. For example, the "responsibilities" enumerated in section 429.423(B)(2) include items such as "establishment of job descriptions and assignment of staff . . . [and] maint[aining] a complete staffing schedule." 130 Mass. Code Regs. § 429.423(B)(2). If, as the First Circuit found, MassHealth conditions payment on compliance with section 429.423(B)(2), this creates potential FCA liability for failing to establish a job description for a staff member or failing to maintain a schedule even for a short period of time. This absurd result cannot be the law.

For the same reasons, the First Circuit's reliance on a reference to "adequate" psychiatric staff in concluding that respondents plausibly alleged a separate violation of section 429.423(B)(2) is equally misplaced. That the clinic director is responsible for employing "adequate" psychiatric staff is not a "requirement," but is merely a "responsibility," as discussed above. In addition, the First Circuit concluded that Arbour's psychiatrist was not "adequate" only based upon separate regulations requiring that a psychiatrist be board certified. *See* Pet. App. 21 (citing 130 Mass. Code Regs. § 429.422(A); 105 Mass. Code Regs. § 140.530(C)(1)(a)). The actual condition of payment, section 429.439, does not even reference any of these regulations, and does not otherwise define what qualifications a psychiatrist must have to be "adequate."

In short, the First Circuit engaged in a cut-and-paste approach, "weav[ing] together" isolated phrases

of separate regulations to find that respondents had alleged violations of conditions of payment. *Hobbs*, 711 F.3d at 714. Because MassHealth has not expressly identified section 429.423(B)(2) as a condition of payment, the Court should grant certiorari and reverse the First Circuit's decision.

IV. The Viability and Scope of "Implied Certification" FCA Liability Present Important and Recurring Questions of Federal Law That This Court Should Decide

The courts of appeals are frequently confronted with FCA claims premised on implied certification theories of liability. While courts of appeals address such claims in wildly inconsistent ways, this Court has yet to address (1) the viability of such claims; or (2) whether the condition of payment prerequisite to pleading such claims must be expressly stated.

This Court should grant certiorari because this case presents important questions of federal law. New FCA complaints have increased substantially in the past thirty years. In particular, actions commenced by whistleblowers have increased dramatically. In fiscal year 1987, relators commenced 30 *qui tam* actions, while in fiscal year 2014, relators commenced 713 *qui tam* actions. U.S. Dep't of Justice, *Fraud Statistics—Overview* (Nov. 20, 2014), http://www.justice.gov/civil/pages/attachments/2014/11/21/fcastats.pdf. These cases implicate millions and sometimes billions of dollars in potential recoveries. *Id.*

Moreover, FCA cases of this type—alleging "legally false" claims based on an "implied certification" theory, rather than "factually false" claims based on actual false statements on claim forms—are rising. *See* W.

Jay DeVecchio, *The False Claims Act and Data Rights: What Plaintiffs' Lawyers Need to Know but Do Not Want to Hear*, 43 Pub. Cont. L.J. 467, 470 (2014). The Court should therefore (1) address whether implied certification claims are viable, and hold that they are not; or, alternatively (2) establish a uniform standard for when implied certification cases may be brought and hold that to defeat a motion to dismiss, an FCA plaintiff must plausibly allege that the defendant violated an express condition of payment.

CONCLUSION

For the foregoing reasons, the Court should grant the petition for certiorari.

June 2015

Respectfully submitted,

MARK W. PEARLSTEIN
LAURA MCLANE
EVAN D. PANICH
MCDERMOTT WILL & EMERY LLP
28 State Street
Boston, MA 02109
(617) 535-4000

M. MILLER BAKER
Counsel of Record
MCDERMOTT WILL & EMERY LLP
500 North Capitol Street, NW
Washington, DC 20001
(202) 756-8000
mbaker@mwe.com

Counsel for Petitioner

APPENDIX

TABLE OF CONTENTS

APPENDIX A

United States Court of Appeals,
For the First Circuit.

No. 14–1423

UNITED STATES and COMMONWEALTH OF MASSACHUSETTS ex rel. JULIO ESCOBAR and CARMEN CORREA, Administratrix of the Estate of Yarushka Rivera,

Plaintiffs, Appellants,

v.

UNIVERSAL HEALTH SERVICES, INC.,

Defendant, Appellee.

APPEAL FROM THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MASSACHUSETTS

[Hon. Douglas P. Woodlock, U.S. District Judge]

Before
Howard, Stahl, and Barron,
Circuit Judges

Matthew P. McCue, with whom *Law Office of McCue* was on brief, for appellants.

Mark W. Pearlstein, with whom *Laura McLane*, *Evan D. Panich*, and *McDermott Will & Emery LLP* were on brief, for appellee.

Robert Ross, with whom *Steven Sharobem* and *Martha Coakley*, Attorney General, were on brief, for Commonwealth of Massachusetts, amicus curiae.

Jennifer M. Verkamp and *Morgan Verkamp LLC*, on brief for Taxpayers Against Fraud Education Fund, amicus curiae.

March 17, 2015

Opinion

STAHL, *Circuit Judge*.

The genesis of this False Claims Act case was the care of Relators' daughter at Arbour Counseling Services in Lawrence, Massachusetts. Relators alleged that their daughter—who died of a seizure in 2009—was treated by various unlicensed and unsupervised staff, in violation of state regulations. The crux of their complaint is that Arbour's alleged noncompliance with sundry supervision and licensure requirements rendered its reimbursement claims submitted to the state Medicaid agency actionably false under both the federal and Massachusetts False Claims Acts.

The district court dismissed the complaint pursuant to Federal Rule of Civil Procedure 12(b)(6). With one limited exception, we reverse.

I. Facts & Background

A. *Regulatory framework*

Arbour Counseling Services ("Arbour"), owned and operated by Defendant–Appellee Universal Health Services, Inc. ("UHS"), is a provider of mental-health services in Lawrence, Massachusetts.[1] Arbour participates in the state Medicaid program, known as MassHealth, and bills MassHealth for services rendered to individuals insured by the program.

The state has promulgated regulations governing the MassHealth program. *See generally* 130 Mass.Code Regs. §§ 401.401–650.035.[2] Chapter 429 in particular pertains to the provision of mental-health services at both "parent centers" and "satellite facilities" around the state.[3] In the regulations, a satellite facility, such as the Arbour clinic at issue in this case, is a "mental health center program at a different location from the parent center that operates under the license of and falls under the fiscal, administrative, and personnel management of the parent center." *Id.* § 429.402. Satellite facilities are classified as either "autonomous" or "dependent"; autonomous facilities have "sufficient

---

[1] We use the name "Arbour" here to refer specifically to the clinic that treated Yarushka Rivera in Lawrence.

[2] The most up-to-date version of the Code of Massachusetts Regulations are accessible at http://www.mass.gov/courts/case-legal-res/law-lib/laws-by-source/cmr/ (last visited March 5, 2015).

[3] Chapter 429 sets forth regulations specific to the provision of mental-health services. For administrative and billing regulations generally applicable to all MassHealth providers, see Chapter 450, 130 Mass.Code Regs. §§ 450.101–450.331.

staff and services to substantially assume [their] own clinical management independent of the parent center," while dependent facilities operate "under the direct clinical management of the parent center." *Id.*

The regulations contemplate that mental health centers will employ qualified "core" staff members engaged in disciplines such as psychiatry, psychology, social work, and psychiatric nursing. *See id.* § 429.422 (setting forth staff composition requirements); *id.* § 429.424 (setting forth requisite staff qualifications). All staff must receive supervision within a formalized relationship, commensurate to the individual's skill and level of professional development. *Id.* § 429.438(E). Noncore counselors and unlicensed staff in particular "must be under the direct and continuous supervision of a fully qualified professional staff member trained in one of the core disciplines." *Id.* § 429.424(F).

Satellite programs are subject to additional regulations regarding staff supervision and integration with parent centers; MassHealth payment for rendered services is conditioned on the satellites' compliance with these provisions. *Id.* § 429.439. As Arbour's Lawrence clinic is a satellite of a parent center located in Malden, Relators' claims are largely premised on a failure to conform to the strictures of the satellite-specific regulation.

B. ***Facts relevant to Relators' claims against UHS***

Relators' daughter, Yarushka Rivera[4]—a teenage recipient of MassHealth benefits—began seeing Arbour

---

[4] Yarushka Rivera was the daughter of Relator Carmen Correa and the stepdaughter of Relator Julio Escobar.

counselor Maria Pereyra in 2007 after experiencing behavioral problems at school. Pereyra, though on staff at Arbour, had no professional license to provide mental-health therapy. Relators met with Pereyra's supervisor, clinical director Edward Keohan, after Yarushka complained that she was not benefiting from counseling. During the meeting, Relators became concerned that Keohan was not supervising Pereyra and was unfamiliar with Yarushka's treatment.

Yarushka was eventually transferred to another staff member, Diana Casado, also ostensibly supervised by Keohan. Like Pereyra, Casado was unlicensed. Relators quickly became unsatisfied with her treatment of their daughter and believed that Casado was not being properly supervised.

In February 2009, Yarushka was once again assigned to a new therapist, Anna Fuchu. Fuchu held herself out as a psychologist with a Ph.D., though Relators later learned that she had trained at an unaccredited online school and that her application for a professional license had been rejected. Notwithstanding Fuchu's lack of essential credentials, she treated Yarushka and eventually diagnosed her with bipolar disorder.

Several months later, when Yarushka's behavioral problems had not abated, officials at her school informed Relators that she would be permitted to attend classes only if she saw a psychiatrist. When Relators told this to Fuchu, she referred Yarushka to Maribel Ortiz, another staff member at Arbour. Believing Ortiz to be a psychiatrist, Relators referred to her as "Dr. Ortiz." They eventually discovered, however, that she was not a psychiatrist, but rather a

nurse, and that she was not under the supervision of the one Arbour staff psychiatrist, Maria Gaticales—herself not board-certified, or eligible for board certification, as contemplated by the regulations. *See* 130 Mass.Code Regs. § 429.424(A)(1). Nonetheless, on May 6, 2009, Ortiz prescribed a medication called Trileptal for Yarushka's purported bipolar disorder.

Yarushka soon experienced an adverse reaction to the drug. Although she called Ortiz for guidance, her two phone messages went unreturned. When her condition worsened, Yarushka decided to discontinue the medication, having not heard from anyone at Arbour in several days. On May 13, Yarushka had a seizure and was hospitalized.

In the days following Yarushka's seizure, Relators spoke with Keohan and voiced their dissatisfaction with their daughter's care. Yarushka's stepfather Julio Escobar "began to suspect that no-one at Arbour was supervising Ms. Ortiz when Mr. Keohan claimed to have no knowledge of the Relators [sic] repeated efforts to reach Ms. Ortiz, and of Yarushka's recent seizure." After their conversation, Keohan directed the staff psychiatrist Gaticales to supervise Ortiz. Yarushka resumed treatment at Arbour, but suffered another seizure in October 2009, this one fatal.

After Yarushka's death, Relators spoke with Anna Cabacoff, a social worker at Arbour who had worked with Yarushka in the past. Cabacoff informed them that the counselors who had cared for Yarushka were not properly licensed to provide treatment without supervision or to prescribe medication, and that

Gaticales was not board-certified[5] and accordingly unqualified to supervise the other staff members.

In the months following the death of their daughter, Relators filed complaints with several state agencies, including the Disabled Persons Protection Committee ("DPPC"), Division of Professional Licensure ("DPL"), and the Department of Public Health ("DPH"). Although the ensuing DPPC report found that there was insufficient evidence of abuse of a disabled person, it concluded that Ortiz and Gaticales "may have been" out of compliance with relevant requirements concerning qualifications and supervision.

DPH determined, after an investigation, that Arbour had violated fourteen distinct regulations, including those relating to staff supervision and licensure.[6] The DPH report deemed Relators' allegations "valid" and found that

> [t]he Psychiatrist's personnel record indicated that she was not qualified to supervise a nurse practitioner because she was not Board Certified in psychiatry. Clinical Therapist # 8's and Clinical Therapist # 11's personnel files indicated they were not licensed. Clinic Director # 2 said that he supervised Clinical Therapist # 8 and Clinical Therapist # 11, but did not document these meetings.

The report also concluded, based on a comprehensive review of Arbour's personnel files, that "23 therapists

---

[5] Relators confirmed this by checking state licensing databases.

[6] Relators attached a copy of the DPH report to their complaint as an exhibit.

were not licensed for independent practice and also ... were not licensed in their discipline." Though all twenty-three therapists required clinical supervision, there was no documentation to show that any had received such supervision prior to January 2012, despite having been hired as early as 1996. As a result of the DPH report, Arbour entered into a plan of correction with the agency to rectify the identified deficiencies.

In addition, Arbour's clinical director Keohan entered into a consent agreement with the Board of Registration of Social Workers, within the DPL.[7] In the agreement, Keohan admitted to sufficient facts meriting the Board's conclusion that, inter alia, he had authorized Pereyra's unlicensed practice of social work at the clinic, in violation of Massachusetts law. As a consequence, the agreement imposed a two-year period of supervised probation on Keohan's license to practice social work in the state. Fuchu, another staff member who had treated Yarushka, also entered into a consent agreement wherein she admitted to holding herself out as a psychologist despite not being licensed. She agreed to pay a $1,000 civil penalty.

C. *Procedural background*

Relators filed their second amended complaint in February of 2013, reciting the above allegations and setting forth fourteen counts against Defendant UHS under both the federal and Massachusetts False

---

[7] A copy of this agreement was attached to the complaint as an exhibit.

Claims Acts.[8] The complaint alleged that Arbour, in submitting bills for services rendered by Pereyra, Casado, Fuchu, and Ortiz—in connection with the treatment of Yarushka Rivera and other MassHealth recipients—fraudulently misrepresented that those staff members were properly licensed and/or supervised, as required by law. The complaint further alleged that Arbour made similar fraudulent misrepresentations with regard to additional unidentified clinical staff members and nurse practitioners, who had treated patients other than Yarushka. Finally, Relators alleged that Arbour had engaged in fraudulent billing "during [a] period of non-compliance with core staff and supervision requirements," insofar as the clinic had failed to employ at least one fully certified psychiatrist and one fully certified psychologist.

The district court dismissed the complaint in its entirety. In determining whether Relators had pleaded the requisite element of falsity, the court drew a distinction between requirements that MassHealth imposes on providers as preconditions to reimbursement ("conditions of payment") and those imposed as preconditions to participation in the program in the first instance ("conditions of participation"). The court held that only noncompliance with the former could establish the falsity of a claim. Relying on chapter 429's preamble, which states in part

---

[8] The federal and state governments declined to intervene on behalf of Relators in the district court, but the Commonwealth of Massachusetts as amicus curiae was permitted to participate in oral argument before this court.

that "130 CMR 429.000 establishes requirements for participation of mental health centers in MassHealth,"[9] the court observed that the chapter "generally does not establish preconditions to payment." *United States ex rel. Escobar v. Universal Health Servs., Inc.*, No. 11–11170–DPW, 2014 WL 1271757, at *7 (D. Mass. Mar. 26, 2014). The court then evaluated the text of individual regulations cited in the complaint to determine whether they constituted conditions of participation or of payment. The court analyzed the regulations "through the lens" of the preamble, effectively assuming that each regulation imposed only a condition of participation, "unless its 'plain provisions' suggest[ed] that it is also a precondition of payment." *Id.*

Applying that rubric, the district court ruled that Relators' claims failed on the merits, since there was "no indication" in the text of any of the pertinent regulations that they were intended as conditions of payment, rather than as conditions of participation as stated in the preamble. *Id.* at *7–8. The only exception was the overarching regulation pertaining to satellite

---

[9] The full text of the preamble is as follows:

> 130 CMR 429.000 establishes requirements for participation of mental health centers in MassHealth and governs mental health centers operated by freestanding clinics, satellite facilities of clinics, and identifiable units of clinics. All mental health centers participating in MassHealth must comply with the MassHealth regulations, including but not limited to MassHealth regulations set forth in 130 CMR 429.000 and 450.000: *Administrative and Billing Regulations.*

130 Mass.Code Regs. § 429.401.

centers—section 429.439—which states that "[s]ervices provided by a satellite program are reimbursable only if the program meets the standards described below." *See id.* at *9. The court went on to note that section 429.439 sets forth different requirements for autonomous and dependent satellite programs; because Relators had failed to plead whether the Lawrence Arbour clinic was autonomous or dependent, the court held that the complaint did not plead with particularity a misrepresentation of compliance with any condition of payment, as required by Federal Rule of Civil Procedure 9(b). *Id.* at *10, *12. The court also held that the counts of the complaint directed at unnamed staff members and Arbour's pattern of noncompliance with core staffing requirements also failed to allege fraud with particularity. *Id.* at *12–13.

Relators now appeal from the dismissal of their complaint.

II. Analysis

A. *False Claims Act generally*

The False Claims Act ("FCA" or "Act") is an "expansive [ ]" statute, intended "to reach all types of fraud, without qualification, that might result in financial loss to the Government." *Cook Cnty., Ill. v. United States ex rel. Chandler,* 538 U.S. 119 (2003) (internal quotation marks omitted). As relevant here, the Act proscribes "knowingly present[ing], or caus[ing] to be presented, a false or fraudulent claim for payment or approval."[10] 31 U.S.C. § 3729(a)(1)(A). To be

[10] The statute provides that "the terms 'knowing' and 'knowingly' ... mean that a person, with respect to information ... (i) has actual

actionable, a false or fraudulent statement must be material to the government's decision to pay a claim. *United States ex rel. Loughren v. Unum Grp.,* 613 F.3d 300, 307 (1st Cir. 2010). The Act's qui tam provisions authorize private individuals to sue on behalf of the United States in order to recover monies alleged to have been defrauded from the government. 31 U.S.C. § 3730(b); *United States ex rel. Duxbury v. Ortho Biotech Prods., L.P.,* 719 F.3d 31, 33 (1st Cir. 2013).

In defining the notion of "falsity" under the FCA, which the statute itself does not do, a number of circuits have developed two categories of false submissions: those that are factually false and those that are legally false. *See, e.g., United States ex rel. Conner v. Salina Reg'l Health Ctr., Inc.,* 543 F.3d 1211, 1217 (10th Cir. 2008); *Mikes v. Straus,* 274 F.3d 687, 696–97 (2d Cir. 2001). Courts have further subdivided claims in the latter group based on whether they proceed on a theory of either "implied" or "express" certification of compliance with conditions of payment. *See United States ex rel. Wilkins v. United Health Grp., Inc.,* 659 F.3d 295, 305–06 (3d Cir. 2011) (collecting cases).

This circuit recently has eschewed distinctions between factually and legally false claims, and those between implied and express certification theories, reasoning that they "create artificial barriers that

---

knowledge of the information; (ii) acts in deliberate ignorance of the truth or falsity of the information; or (iii) acts in reckless disregard of the truth or falsity of the information." 31 U.S.C. § 3729(b)(1)(A). No proof of specific intent to defraud is required. *Id.* § 3729(b)(1)(B).

obscure and distort [the statute's] requirements." *United States ex rel. Hutcheson v. Blackstone Med., Inc.,* 647 F.3d 377, 385 (1st Cir. 2011). Instead, "we take a broad view of what may constitute a false or fraudulent statement to avoid 'foreclos[ing] FCA liability in situations that Congress intended to fall within the Act's scope.' " *United States ex rel. Jones v. Brigham & Women's Hosp.,* 678 F.3d 72, 85 (1st Cir. 2012) (alteration in original) (quoting *Hutcheson,* 647 F.3d at 387). We ask simply whether the defendant, in submitting a claim for reimbursement, knowingly misrepresented compliance with a material precondition of payment. *New York v. Amgen Inc.,* 652 F.3d 103, 110 (1st Cir. 2011). Preconditions of payment, which may be found in sources such as statutes, regulations, and contracts, need not be "expressly designated." *Hutcheson,* 647 F.3d at 387–88. Rather, the question whether a given requirement constitutes a precondition to payment is a "fact-intensive and context-specific inquiry," *Amgen,* 652 F.3d at 111, involving a close reading of the foundational documents, or statutes and regulations, at issue. *Cf. United States v. Sci. Applications Int'l Corp.,* 626 F.3d 1257, 1269 (D.C. Cir. 2010) [hereinafter "*SAIC* "] ("The existence of express contractual language specifically linking compliance to eligibility for payment may well constitute dispositive evidence of materiality, but it is not ... a necessary condition.").[11]

---

[11] *But see, e.g., Mikes v. Straus,* 274 F.3d 687, 700 (2d Cir. 2001) (FCA claim proceeding under theory that defendant misrepresented compliance with program requirement "is appropriate[ ] ... only when the underlying statute or regulation

B. *Establishing "falsity"*

The district court—whose decision we review de novo, *Amgen,* 652 F.3d at 109—acknowledged our rejection in *Hutcheson* of "judicially created formal categories," 647 F.3d at 385, but held that the distinction between conditions of participation and conditions of payment nonetheless survived; only misrepresentation of compliance with the latter would establish that a claim was false within the meaning of the FCA. The court reasoned that, because the holdings of both decisions were framed in terms of conditions of payment, *Hutcheson* and the subsequent case of *Amgen* at least implicitly accepted the "condition of payment/condition of participation dichotomy." *Escobar,* 2014 WL 1271757, at *6; *see Amgen,* 652 F.3d at 110 ("To survive [a] 12(b)(6) motion, [plaintiffs].... must show that the claims at issue in [the] litigation misrepresented compliance with a material precondition of Medicaid payment such that they were false or fraudulent."); *Hutcheson,* 647 F.3d at 379 ("[W]e hold that [the] 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...."). The court also pointed to cases from other circuits that have adopted such a framework. *Escobar,* 2014 WL 1271757, at *6 n. 1 (citing cases from Second and Sixth Circuits).

To be sure, *Hutcheson* and *Amgen* held that a plaintiff states a claim under the FCA when he or she

---

upon which the plaintiff relies *expressly* states the provider must comply in order to be paid").

alleges that a recipient of government funds has misrepresented its compliance with a condition of payment. But while the district court concluded that *only* claims premised on misrepresentation of compliance with a condition of payment are cognizable under the FCA, we find that any payment/participation distinction is not relevant here. As in *Amgen,* the provisions at issue in this case clearly impose conditions of payment.

Section 429.439 of the MassHealth regulations expressly provides that "[s]ervices provided by a satellite program are reimbursable only if the program meets the standards described below [in subsections (A) through (D)]." Subsection (A) pertains to parent centers' supervision of satellite programs, while subsection (B) addresses the supervision that must occur *within* autonomous satellites, which "must provide supervision and in-service training to all noncore staff employed at the satellite program."[12] Subsection (C) further demands that all satellites employ a full-time clinical director who meets the qualifications required of core staff members in his or her discipline, as set forth in section 429.424; in addition, supervisors at dependent satellites must "receive regular supervision and consultation from qualified core staff at the parent center."

---

[12] 130 Mass.Code Regs. § 429.402 defines a "core team" as a "group of three or more mental-health professionals that must include a psychiatrist and one each of at least two of the following professionals: clinical or counseling psychologist, psychiatric social worker, or psychiatric nurse."

Relying on subsection (B), the district court read section 429.439 as imposing internal supervision requirements *only* on autonomous satellites. In so doing, the district court overlooked a critical interaction between section 429.439 and other substantive provisions of the MassHealth regulations: subsection (C) specifies that the clinical director of both autonomous and dependent satellites must "meet all of the requirements in 130 CMR 429.423(B)." Section 429.423(B), in turn, delineates the clinical director's responsibilities, including, inter alia, "overall supervision of staff performance."

Therefore, the MassHealth regulations explicitly condition the reimbursement of satellites' claims on the clinical director's fulfillment of his or her regulatory duties, regardless of whether the satellite is autonomous or dependent. Section 429.423(B) makes plain that one of those duties is ensuring appropriate supervision. Indeed, the cost of staff supervision is automatically built into MassHealth reimbursement rates. *See* 130 Mass.Code Regs. § 429.408(C)(3). That supervision at Arbour was either grossly inadequate or entirely lacking is the core of Relators' complaint. Insofar as Relators have alleged noncompliance with regulations pertaining to supervision, they have provided sufficient allegations of falsity to survive a motion to dismiss.

C. *Application to Relators' complaint*

1. *Counts I–IV and VIII–XI*

In Counts I through IV and VIII through XI,[13] Relators allege that four different individuals who treated Yarushka Rivera (Pereyra, Casado, Fuchu, and Ortiz) did not receive proper supervision, either directly from the clinical director Keohan or from the psychiatrist Gaticales—who, in any event, was not board-certified. *See* 130 Mass.Code Regs. §§ 429.423(D), 429.424(A), 429.424(F), 429.438(E). In these counts, Relators have adequately pleaded that Arbour's claims for reimbursement in connection with Yarushka's treatment were false within the meaning of the Act, in that they misrepresented compliance with a condition of payment, i.e., proper supervision.[14]

---

[13] Counts VIII through XI are the same as Counts I through IV, but they bring claims under the Massachusetts FCA rather than the federal statute. "Given the substantive similarity of the [Massachusetts] FCA [ ] ... and the federal FCA with respect to the provisions at issue in this litigation, the state statute[ ] may be construed consistently with the federal act." *See New York v. Amgen, Inc.,* 652 F.3d 103, 109 & n. 6 (1st Cir. 2011); *Scannell v. Att'y Gen.,* 70 Mass.App.Ct. 46, 49 n. 4, 872 N.E.2d 1136 (2007) ("[T]he MFCA was modeled on the similarly worded Federal False Claims Act.").

[14] Although the record is silent as to whether Arbour explicitly represented that it was in compliance with conditions of payment when it sought reimbursement from MassHealth, we have not required such "express certification" in order to state a claim under the FCA. *See United States ex rel. Hutcheson v. Blackstone Med., Inc.,* 647 F.3d 377, 385–86 (1st Cir. 2011) (rejecting labels of express and implied certification). We note, however, that each time it submitted a claim, Arbour implicitly communicated that it

These counts also have properly pleaded that the condition of payment at issue was a material one. The express and absolute language of the regulation in question, in conjunction with the repeated references to supervision throughout the regulatory scheme, " 'constitute dispositive evidence of materiality.' " *Hutcheson,* 647 F.3d at 394 (quoting *SAIC,* 626 F.3d at 1269); *see* 130 Mass.Code Regs. § 429.439 ("Services provided by a satellite program are reimbursable only if the program meets the standards described below.").

Furthermore, Relators have satisfied the scienter requirement, as they have plausibly pleaded that Arbour knowingly submitted false claims to MassHealth. The complaint quotes a portion of Keohan's interview with the state DPH in which he admitted that, until recently, he was "unaware that supervision was required to be provided on a regular and ongoing bases, or that the supervision meetings needed to be documented." These allegations more than suffice to establish that Arbour acted in reckless disregard or deliberate ignorance of the falsity of the information contained in the claims. *See* 31 U.S.C. § 3729(b)(1)(A); *cf. Loughren,* 613 F.3d at 313–14.

These counts were pleaded with sufficient particularity. In the FCA context, Federal Rule of Civil Procedure 9(b) requires relators to connect allegations of fraud to particular false claims for payment, rather than a fraudulent scheme in the abstract. *United States ex rel. Karvelas v. Melrose–Wakefield Hosp.,* 360 F.3d 220, 232 (1st Cir. 2004). While we have declined to set

---

had conformed to the relevant program requirements, such that it was entitled to payment.

forth a mandatory checklist, we have identified a number of types of information that contribute to the particularity of the allegations, including:

> the dates of the claims, the content of the forms or bills submitted, their identification numbers, the amount of money charged to the government, the particular goods or services for which the government was billed, the individuals involved in the billing, and the length of time between the alleged fraudulent practices and the submission of claims based on those practices.

Id. at 233.

Relators' complaint sets forth the core of this material: it alleges twenty-seven separate dates on which claims were submitted in connection with Yarushka's care, each time including the relevant billing codes, amount invoiced, and the name of the Arbour staff member who provided the treatment for which reimbursement was sought. Relators have thus succeeded in linking their allegations of fraud to specific claims for payment. *Cf. United States ex rel. Ge v. Takeda Pharm. Co. Ltd.*, 737 F.3d 116, 124 (1st Cir. 2013) (affirming dismissal of FCA complaint for failure to state fraud with particularity where relator "alleged next to no facts in support of the proposition that [pharmaceutical company's] alleged misconduct resulted in the submission of false claims or false statements material to government payment").

Finally, we note that while Relators' complaint provides specific information about bills submitted to MassHealth in connection with Yarushka's care only, it also seeks damages for bills submitted for services rendered to all MassHealth recipients by Pereyra,

Casado, Fuchu, and Ortiz within a six-year period. Under the circumstances of this case, where Relators have raised a particular and plausible allegation of fraud in connection with the treatment of their daughter, we do not view the absence of more precise details pertaining to the bills for services provided to other MassHealth recipients as an impediment to proceeding. Given that such allegation is not particular to Yarushka's treatment, but rather arises from the clinical director's systematic failure to enforce supervision requirements, it stands to reason that billing for more than one MassHealth recipient has been infected by fraud.

2. *Counts VII and XIV*

For similar reasons, Counts VII and XIV of Relators' complaint also survive a motion to dismiss. The substance of those counts is that Arbour violated both the federal and Massachusetts FCA by fraudulently misrepresenting its compliance with regulations requiring mental-health clinics to employ at least one board-certified psychiatrist at all times.[15]

---

[15] At different points in their complaint, Relators identify both MassHealth and Department of Public Health ("DPH") regulations as the source of this staffing requirement. There is at least some ambiguity as to whether the MassHealth regulation in question, 130 Mass.Code Regs. § 429.422, independently requires each satellite clinic to employ its own psychiatrist. Section 429.422 provides that *mental health centers* must employ at least one psychiatrist. A "mental health center" is defined as "an entity that delivers a comprehensive group of diagnostic and psychotherapeutic treatment services to mentally or emotionally disturbed persons and their families by an interdisciplinary team under the medical direction of a psychiatrist." 130 Mass.Code

See 130 Mass.Code Regs. § 429.422(A); 105 Mass.Code Regs. § 140.530(C)(1)(a). Since the clinical director is explicitly responsible for hiring adequate psychiatric staff, *see* 130 Mass.Code Regs. § 429.423(B)(2)(e), and claims are reimbursable only if the clinical director fulfills the assigned duties, *see id.* § 429.439(C), Arbour's failure to maintain a properly licensed psychiatrist on staff constituted noncompliance with a

---

Regs. § 429.402. This definition appears to refer to an entity comprising *both* the parent center and the satellite locations. *See* 130 Mass.Code Regs. § 429.402 (defining "parent center" as "the central location of the *mental health center*...."; defining "autonomous satellite program" and "dependent satellite program" as "a *mental health center* program....") (emphases added). On this reading of the definition of "mental health center," a satellite that does not employ a psychiatrist is not out of compliance with the staffing regulation so long as the parent has a psychiatrist on staff.

But the DPH regulations suggest something else. 105 Mass.Code Regs. § 140.530 provides that every "clinic providing mental health services" must employ a board-certified psychiatrist, or one who is eligible for board certification. "A satellite clinic must meet [this requirement] independently of its parent clinic." 105 Mass.Code Regs. § 140.330. According to the DPH report attached to Relators' complaint, which details the results of the agency's investigation of the satellite clinic where Yarushka Rivera received treatment, that clinic was not in compliance with the staffing requirements of 105 Mass.Code Regs. § 140.530. We defer to the agency's determination that such regulation applies to the Arbour satellite clinic at issue here. *See City of Pittsfield, Mass. v. U.S. Envt'l Prot. Agency,* 614 F.3d 7, 10–11 (1st Cir. 2010) (giving "controlling weight" to "agency's interpretation [of its own regulation] unless it is plainly erroneous or inconsistent with the regulation") (internal quotation marks omitted); *Friends & Fishers of Edgartown Great Pond, Inc. v. Dep't of Envt'l Prot.,* 446 Mass. 830, 838, 848 N.E.2d 393 (2006) (deferring to agency's interpretation of its own regulations).

material condition of payment. Such noncompliance was at least deliberately ignorant, in light of Relators' allegation that they were able to determine that Gaticales was not board-certified in psychiatry simply by checking a state licensing database. Thus, these counts, too, were improperly dismissed.[16]

3. *Counts V–VI and XII–XIII*

We are left with Counts V, VI, XII, and XIII, which allege that Arbour engaged in fraudulent billing in connection with other unlicensed and unsupervised clinical staff and nurse practitioners. Relators allege that the "specific identit[ies]" of these staff members are "currently unknown to [them] but [are] well known to Arbour."

We have previously upheld the dismissal of claims under the FCA for failure to plead fraud with particularity where, among other things, the individuals involved with allegedly improper billing were not identified. *See, e.g., Karvelas,* 360 F.3d at 233.

---

[16] These counts also allege that Arbour violated core staffing requirements by failing to have at least one licensed psychologist on staff. However, the regulations do not mandate that a psychologist be on staff at all times; instead, clinics are required to employ at least two people from various disciplines, one of which is psychology. 130 Mass.Code Regs. § 429.422(A); 105 Mass.Code Regs. § 140.530(C)(2)(b).

Although Fuchu held herself out as a licensed psychologist when she in fact was not, the complaint does not allege whether Arbour retained any other properly licensed psychologists, or staff in other approved disciplines. Thus, the portions of Counts VII and XIV that allege that Arbour committed fraud by failing to have at least one licensed psychologist on staff does not state a plausible claim for relief.

Here, however, while the staff members in question have not been identified by name in the individual counts, the factual background of the complaint sets forth a non-exhaustive list of twenty-two Arbour employees who have obtained a National Provider Identification number despite not being licensed as social workers or mental-health counselors by the Commonwealth of Massachusetts. Moreover, the DPH report attached to the complaint verifies that twenty-three Arbour therapists "were not licensed for independent practice and also ... were not licensed in their discipline," and had received no documented supervision prior to January 2012. These concrete allegations, corroborated by a state agency's independent report and Keohan's own admission that the clinic suffered from a fundamental lack of oversight, confirm that the basic goals of Federal Rule of Civil Procedure 9(b) have been met—"to provide a defendant with fair notice of a plaintiff's claim, to safeguard a wrongdoing, and to protect a defendant against the institution of a strike suit." *Suna v. Bailey Corp.,* 107 F.3d 64, 68 (1st Cir. 1997) (internal quotation marks omitted); *cf. Ge,* 737 F.3d at 123 (observing that particularity requirement of Rule 9(b) is designed to ward off "parasitic relators who bring FCA damages claims based on information within the public domain or that the relator did not otherwise discover" (internal quotation marks omitted)). Under the circumstances, then, these counts of Relators' complaint also state claims under the FCA.

III. Conclusion

Compliance with the regulations at issue pertaining to staff supervision and core staffing at satellite centers is a condition of payment by MassHealth. Because our case law makes clear that a healthcare provider's noncompliance with conditions of payment is sufficient to establish the falsity of a claim for reimbursement, we need not address here whether the False Claims Act embraces a distinction between conditions of payment and conditions of participation.

In the final analysis, Relators' daughter died after receiving treatment that was out of compliance with over a dozen regulations, as determined by an independent report. Relators have carefully compiled information regarding the names of unlicensed and unsupervised providers, and the dates, amounts, and codes of allegedly false claims submitted to MassHealth. As such, they have appropriately stated a claim with particularity under the FCA.

We accordingly *REVERSE* the dismissal of Relators' complaint, save for that portion of Counts VII and XIV pertaining to the employment of psychologists. *See supra* note 16. We remand the case for proceedings consistent with this opinion. Costs are awarded to Relators.

APPENDIX B

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHSETTS

UNITED STATES of AMERICA and THE COMMONWEALTH OF MASSACHUSETTS, EX REL JULIO ESCOBAR, and CARMEN CORREA, ADMINISTRATRIX OF THE ESTATE OF YARUSHKA RIVERA

Plaintiffs,
v.
UNIVERSAL HEALTH SERVICES, INC.,

Defendant.

Civil Action No. 11–11170–DPW

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. Igbal,* 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,* 70 Mass. App. Ct. 46, 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]

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

---

[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 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.").

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.

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,* 405 Mass. 390, 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 parentsatellite 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

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

---

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." *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.

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* 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

APPENDIX C

UNITED STATES COURT OF APPEALS
FOR THE FIRST CIRCUIT

No. 14-1423

UNITED STATES, EX REL. JULIO ESCOBAR;
CARMEN CORREA, ADMINISTRATRIX OF THE ESTATE OF
YARUSHKA RIVERA

Plaintiff - Appellants

COMMONWEALTH OF MASSACHUSETTS

Defendant - Appellee

BEFORE

LYNCH, CHIEF JUDGE,
TORRUELLA, STAHL, HOWARD, THOMPSON,
KAYATTA AND BARRON,
CIRCUIT JUDGES.

ORDER OF COURT

Entered: April 14, 2015

The petition for rehearing having been denied by the panel of judges who decided the case, and the petition for rehearing en banc having been submitted to the active judges of this court and a majority of the judges not having voted that the case be heard en banc, it is

ordered that the petition for rehearing and the petition for rehearing en banc be denied.

By the Court:

/s/ Margaret Carter, Clerk

APPENDIX D

130 Code of Massachusetts Regulations 429.439

429.439: Satellite Programs

Services provided by a satellite program are reimbursable only if the program meets the standards described below.

(A) A satellite program must be integrated with the parent center in the following ways.

(1) The administrator of the parent center is responsible for ensuring compliance of the satellite program with the regulations in 130 CMR 429.000.

(2) There must be clear lines of supervision and communication between personnel of the parent center and its satellite programs. The parent center must maintain close liaison with its satellite programs through conferences or other methods of communication.

(3) The satellite program must be subject to all the written policies and procedures of the parent center governing the types of services that the satellite program offers.

(4) The satellite program must maintain on its own premises its client records as set forth in 130 CMR 429.436.

(B) An autonomous satellite program must provide supervision and in-service training to all noncore staff employed at the satellite program.

(C) The director of clinical services of the parent center must designate one professional staff member at the satellite program as the satellite's clinical director. The clinical director must be employed on a full-time basis and meet all of the requirements in 130 CMR 429.423(B).

(1) The supervisor of the satellite program must report regularly to the clinical director of the parent center to ensure ongoing communication and coordination of services.

(2) In an autonomous satellite program, the supervisor must meet the qualifications required of a core staff member in his or her discipline, as set forth in 130 CMR 429.424.

(3) In a dependent satellite program, the supervisor must meet the basic qualifications required for his or her discipline, as set forth in 130 CMR 429.424, and receive regular supervision and consultation from qualified core staff at the parent center.

(D) If a dependent satellite program does not offer the entire range of services available at the parent center, the dependent satellite program must refer clients to the parent center or a facility that offers such services. The parent center must determine the necessity for treatment and the appropriateness of the treatment

plan for such clients and institute a clear mechanism through which this responsibility is discharged, by consultation with the satellite program team, regular supervision of the satellite program by supervisory-level professional core staff in the parent center, or by other appropriate means. For staff composition requirements pertaining to dependent satellite programs, see 130 CMR 429.422(D).

APPENDIX E

130 Code of Massachusetts Regulations 429.423

429.423: Position Specifications and Qualifications

(A) Administrator. The mental health center must designate one individual as administrator, who is responsible for the overall operation and management of the center and for ensuring compliance with MassHealth regulations. The administrator must have previous training or experience in personnel, fiscal, and data management, as described in 130 CMR 429.438.

(1) The same individual may serve as both the administrator and clinical director.

(2) In a community health center, the administrator of the entire facility may also administer the mental health center program.

(B) Director of Clinical Services. Mental health centers must designate a professional staff member to be the clinical director who is then responsible to the administrator for the direction and control of all professional staff members and services.

(1) The clinical director must be licensed, certified, or registered to practice in one of the core disciplines listed in 130 CMR 429.424, and must have had at least five years of full-time, supervised

clinical experience subsequent to obtaining a master's degree, two years of which must have been in an administrative capacity. The clinical director must be employed on a full-time basis. When the clinic is licensed as a community health center, the clinical director must work at the center at least half-time.

(2) The specific responsibilities of the clinical director include

(a) selection of clinical staff and maintenance of a complete staffing schedule;

(b) establishment of job descriptions and assignment of staff;

(c) overall supervision of staff performance;

(d) accountability for adequacy and appropriateness of patient care;

(e) in conjunction with the medical director, accountability for employing adequate psychiatric staff to meet the psychopharmalogical needs of clients;

(f) establishment of policies and procedures for patient care;

(g) program evaluation;

(h) provision of some direct patient care in circumstances where the clinical director is one

of the three minimum full-time equivalent staff members of the center;

(i) development of in-service training for professional staff; and

(j) establishment of a quality management program.

(C) Medical Director. The mental health center must designate a psychiatrist who meets the qualifications outlined in 130 CMR 429.424(A) as the medical director, who is then responsible for establishing all medical policies and protocols and for supervising all medical services provided by the staff. The medical director must work at the center a minimum of eight hours a week. When the clinic is licensed as a community health center, the medical director must work at the center at least four hours a week.

(D) Psychiatrist.

(1) The roles and duties of administrator, director of clinical services, and medical director, as detailed in 130 CMR 429.423(A), (B), and (C), may be assumed, all or in part, by a psychiatrist on the center's staff, provided that provision of services to members and performance of all relevant duties in these regulations are carried out to meet professionally recognized standards of health care, as required by MassHealth administrative and billing regulations at 130 CMR 450.000.

(2) The role of the psychiatrist in the center, apart from any duties that may be assumed under 130 CMR 429.423(A), (B), or (C), must include the following:

(a) responsibility for the evaluation of the physiological, neurological, and psychopharmacological status of the center's clients;

(b) involvement in diagnostic formulations and development of treatment plans;

(c) direct psychotherapy, when indicated;

(d) participation in utilization review or quality-assurance activity;

(e) coordination of the center's relationship with hospitals and provision of general hospital consultations as required;

(f) supervision of and consultation to other disciplines; and

(g) clinical coverage on an "on call" basis at all hours of center operation.