No. 15-7

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 Writ Of Certiorari
To The United States Court of Appeals
For The First Circuit

BRIEF FOR THE PETITIONER

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

M. MILLER BAKER
McDermott Will & Emery LLP
500 N. Capitol Street, NW
Washington, DC 20001
(202) 756-8000

ROY T. ENGLERT, JR.
Counsel of Record
GARY A. ORSECK
MARK T. STANCIL
MICHAEL L. WALDMAN
DONALD BURKE
Robbins, Russell, Englert, Orseck, Untereiner & Sauber LLP
1801 K Street, NW
Washington, DC 20006
(202) 775-4500
renglert@robbinsrussell.com

QUESTIONS PRESENTED

1. Whether the "implied certification" theory of legal falsity under the False Claims Act, 31 U.S.C. § 3729 *et seq.*, is viable.

2. 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; 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.

RULE 29.6 STATEMENT

Petitioner Universal Health Services, Inc., has no parent corporation, and no publicly held corporation owns 10% or more, directly or indirectly, of its stock.

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BRIEF FOR THE PETITIONER

OPINIONS BELOW

The opinion of the court of appeals (Pet. App. 1-24) is reported at 780 F.3d 504. The opinion of the district court (Pet. App. 25-53) is unreported.

JURISDICTION

The judgment of the court of appeals was entered on March 17, 2015. A petition for rehearing was denied on April 14, 2015 (Pet. App. 54-55). The petition for a writ of certiorari was filed on June 30, 2015, and was granted on December 4, 2015. The jurisdiction of this Court rests on 28 U.S.C. § 1254(1).

STATUTORY AND REGULATORY PROVISIONS INVOLVED

The relevant portions of the False Claims Act (FCA or Act), 31 U.S.C. § 3729 *et seq.*, and the Code of Massachusetts Regulations are reproduced in the appendix to this brief. App., *infra*, 1a-32a.

INTRODUCTION

This case concerns the "implied-certification" theory of liability under the False Claims Act. It is about when an alleged violation of a statute, regulation, or contract rises to the level of a fraudulent request for payment. The basic outlines of the questions presented can be illustrated with a simple example from common experience.

In a recent filing in this Court, the Solicitor General posed such an example to attempt to justify the implied-certification theory. The Solicitor General's

example is indeed useful—but only to illustrate the fundamental flaw in the theory, and what a Frankenstein's monster the theory can become.

> The Solicitor General argued that
>
> > if a parent promises to pay a child $10 for every hour spent mowing the lawn, and the child returns at the end of the day requesting $20, the child has impliedly represented that the job required two hours' labor—a representation that would be false if the job in fact required only one hour.

Br. for the United States in Opp. 10-11 n.4, *Triple Canopy, Inc.* v. *United States ex rel. Badr*, No. 14-1440 (filed Sept. 8, 2015). But that scenario bears little resemblance to what the implied-certification theory actually allows. It would be a rare (and poorly designed) government program that allows a contractor to request merely an amount of money without specifying the amount of services provided. An implied-certification theory is not needed to deal with the situation in which the amount of goods or services provided is falsely stated by implication rather than expressly, and that is not how the theory is used.

Unlike the Solicitor General's example, the implied-certification theory presumes that the government received the amount of goods or services it paid for, but the contractor failed to abide by some regulatory, statutory, or contractual term while providing the good or service. That theory can be well illustrated by modifying the Solicitor General's example. Suppose that, at age 12, Johnny is given the opportunity to earn a little money by mowing the

lawn. Mom says that she will pay Johnny $10 an hour but that Johnny must honor three conditions every time he mows the lawn: (1) wear protective safety goggles; (2) fill the lawn mower with gas before starting; and (3) mow the lawn only between 3 and 5 p.m., when most of the neighbors will not yet be home from work. Johnny promises Mom that he will always follow all three rules.

At age 14, Johnny mows the lawn one day. He mows between 3:30 and 5:30 p.m., *or* does so wearing no safety goggles, *or* does so without filling the lawn mower with gas first. He tells Mom—truthfully—that he spent two hours mowing the lawn (which was in fact mowed) and asks for $20 payment. He is not asked whether he has followed all of the rules, and does not state that he has done so. Mom pays, but later learns that Johnny did not follow one of the three rules agreed to a couple of years earlier. Confronting Johnny, she learns that Johnny remembers all three rules but chose not to comply with one of them (thus acting knowingly, and with "scienter"). Mom is not sure she would have agreed to pay Johnny if he had not agreed two years earlier to follow all three rules (thus establishing "materiality" as that standard is often applied in FCA cases).

Should Mom give Johnny a stern talking-to to make sure he follows the rules in the future? Should Mom take back some fraction of the $20 she paid Johnny? Or should Mom make Johnny pay her $60, impose an additional punishment (like a "civil penalty") on top of that, and publicly label Johnny a fraudster who has made a "false or fraudulent" demand that Mom pay him for services actually provided? To make the example even stranger—but more like the

False Claims Act—should someone else, say a neighbor who is annoyed by hearing lawnmowers when she gets home from work, get to force punishment and opprobrium on Johnny for breaking Mom's rules, even if Mom chooses not to?

The common sense of the matter is obvious. Mom can appropriately take corrective measures. How severe they are depends on the parent-child relationship and what Mom feels is necessary in the circumstances. But Johnny's failure to comply with the conditions previously established does not render his claim for payment "false or fraudulent." To impose on Johnny treble damages, an additional punishment, and an opprobrious label *in addition to* the calibrated parental remedies and sanctions constitutes ridiculous overkill in the homey hypothetical example.

The legal question presented in this case is whether Congress imposed such draconian remedies and punishments on those who, like Johnny, submit claims that truthfully reflect the services rendered but are supposedly "false" or "fraudulent" because they somehow contain an "implied certification" of compliance with applicable legal duties. The Court will search the text, legislative history, and statutory context in vain for any indication that Congress, in a statute designed to deter and punish real fraud, imposed massive sanctions for every "knowing" violation of a "material" statutory, regulatory, or contractual requirement.

STATEMENT

1. Originally enacted in 1863 "with the principal goal of stopping the massive frauds perpetrated by

large [private] contractors during the Civil War," *Vermont Agency of Nat. Res.* v. *United States ex rel. Stevens*, 529 U.S. 765, 781 (2000) (alteration in original), the False Claims Act imposes liability on any person that has engaged in certain types of fraudulent activity against the federal government. See 31 U.S.C. § 3729(a)(1)(A)-(G). As pertinent here, the Act makes liable any person who "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval." *Id.* § 3729(a)(1)(A). The "claims" subject to the FCA are defined to include "any request or demand * * * for money or property" that is presented to an officer, employee, or agent of the United States." *Id.* § 3729(b)(2)(A)(i). A defendant may be found to have acted "knowingly" if the defendant acts with actual knowledge of false information, in deliberate ignorance of the truth or falsity of information, or with reckless disregard of the truth or falsity of information. *Id.* § 3729(b)(1)(A)(i)-(iii).

FCA liability is "essentially punitive in nature." *Vermont Agency*, 529 U.S. at 784. In particular, the FCA imposes liability for a mandatory civil penalty of between $5,500 and $11,000 for each violation of the Act, as well as treble damages. 31 U.S.C. § 3729(a)(1); 28 C.F.R. § 85.3(a)(9).

Suits under the FCA may be brought either by the Attorney General or by a private person (known as a relator) in the name of the United States, in an action known as a *qui tam* action. 31 U.S.C. § 3730(b)(1). Any *qui tam* complaint must be filed under seal and delivered to the United States, which has 60 days (plus any judicial extensions) to review the complaint and determine whether to intervene.

Id. § 3730(b)(2). If the United States intervenes, the government "shall have the primary responsibility for prosecuting the action." *Id.* § 3730(c)(1). If the United States declines to intervene, the relator may pursue the case independently. *Id.* § 3730(c)(3). In either event, if the *qui tam* action results in the recovery of damages or civil penalties, the recovery (whether by award or settlement) is divided between the government and the relator. *Id.* § 3730(d). The relator in a successful *qui tam* action is also entitled to recover "reasonable expenses" and "reasonable attorneys' fees and costs." *Id.* § 3730(d)(1), (2).[1]

2. This case arises from services provided to relators' daughter, Yarushka Rivera, at a mental health clinic in Lawrence, Massachusetts. The clinic is owned and operated by an indirect subsidiary of petitioner doing business as Arbour Counseling Services. The clinic receives federal and state reimbursement through the Massachusetts Medicaid program, MassHealth. Pet. App. 3-4.

a. The Massachusetts Division of Medical Assistance has promulgated regulations governing mental health centers, like the Lawrence clinic, that par-

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[1] Liability for attorneys' fees and expenses can be substantial. See, *e.g.*, *United States ex rel. Liotine* v. *CDW-Government, Inc.*, No. 3:05–cv–00033, 2013 WL 5366960, at *6 (S.D. Ill. Sept. 25, 2013) (fees and expenses in excess of $3.6 million, following settlement in which United States recovered $7 million); *United States ex rel. Abbott-Burdick* v. *University Medical Assocs.*, No. 2:96-1676-12, 2002 WL 34236885, at *24 (D.S.C. May 23, 2002) (fees and expenses of $2.3 million, following $5.2 million settlement).

ticipate in the MassHealth program. Those regulations appear in Chapter 429.000 of Title 130 of the Massachusetts Code of Regulations, which generally "establishes *requirements for participation* of mental health centers in MassHealth." 130 Mass. Code Regs. § 429.401 (emphasis added). Among other things, the rules govern the scope of services provided at clinics (*id.* § 429.421), the required members of the clinic's staff (*id.* § 429.422), the qualifications necessary to serve in various staff roles (*id.* § 429.424), and general administration of the clinic (*id.* § 429.438).

Several provisions within Chapter 429.000 directly address supervision of staff members. In particular, Section 429.438—captioned "Administration"—states that "[e]ach staff member must receive supervision appropriate to the person's skills and level of professional development." 130 Mass. Code Regs. § 429.438(E)(1). Likewise, in setting forth the required qualifications for clinic staff members occupying each "core discipline" (including psychiatrists, psychologists, social workers, psychiatrist nurses, and counselors), Section 429.424 generally provides that staff members with lesser credentials may practice under the supervision of a more senior staff member. See *id.* § 429.424 (2011).[2] For

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[2] Section 429.424 was amended in 2014. Among other changes, the amendments set forth qualifications for psychiatric nurse mental health clinical specialists, see 130 Mass. Code Regs. § 429.424(E) (2015), and also modified the caption of Section 429.424 to read: "Qualifications of Professional Staff *Authorized to Render Billable Mental Health Center Services* by Core Discipline." (Emphasis added.) The italicized language

example, Section 429.424 states that a licensed physician in her second year of an accredited psychiatric residency program may practice under the "direct supervision of a fully qualified psychiatrist," *id.* § 429.424(A)(2), who is either board certified or eligible and in the process of applying for such certification, see *id.* § 429.424(A)(1). Section 429.424 also specifically contemplates the provision of services by "counselors and unlicensed staff," stating that they "must be under the direct and continuous supervision of a fully qualified professional staff member" who is trained as a psychiatrist, psychologist, social worker, or psychiatric nurse. *Id.* § 429.424(E)(1).

Neither the provisions governing supervision of staff members set forth in Section 429.438(E) nor those set forth in Section 429.424 are designated as preconditions to reimbursement for individual services provided by the mental health center. In marked contrast, another provision in Chapter 429.000 expressly conditions reimbursement for psychological testing services on supervision of unlicensed professionals: "The MassHealth agency pays a center for psychological testing only when," among other things, a certified psychologist "either personally administers the testing or personally supervises such testing during its administration by an unlicensed psychologist." 130 Mass. Code Regs. § 429.441(F)(1). When the state agency wants to

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was not contained in prior versions of Section 429.424. Unless otherwise indicated, all citations in this brief to Section 429.424 are to the version in effect when the relevant events took place.

make a requirement a precondition of payment, it knows how to say so.

Section 429.422—captioned "Staff Composition Requirements"—sets forth rules governing the staff members that certain mental health centers must employ. See 130 Mass Code Regs. § 429.422. Like the staff-supervision provisions in Sections 429.438(E) and 429.424, that regulation does not state that compliance with staffing requirements is a precondition to reimbursement for individual services.

Finally, because the Lawrence clinic is a "satellite facility" connected to another clinic operated by petitioner in Malden, Massachusetts, it is subject to additional regulatory requirements. See Pet. App. 3-4; see also 130 Mass. Code Regs. § 429.402 (defining "Satellite Facility"). These rules, set forth in Section 429.439, are expressly designated as preconditions to reimbursement—again reflecting that the state agency knows how to write regulations that make particular requirements preconditions to payment. See 130 Mass. Code Regs. § 429.439 ("Services provided by a satellite program are reimbursable only if the program meets the standards described below.").

The standards for satellite facilities generally pertain to the relationship between the satellite program and its parent center. See 130 Mass. Code Regs. § 429.439(A) (listing ways in which "satellite program must be integrated with the parent center"); *id.* § 429.439(C) (requiring parent center to "designate one professional staff member at the satellite program as the satellite's clinical director" and defining clinical director's reporting duties and required qualification); *id.* § 429.439(D) (directing

"dependent" satellite facilities to refer certain clients to parent center or other facilities). In addition, an "autonomous" satellite program—*i.e.*, one responsible for its own clinical management, independent of its parent center, see *id.* § 429.402—must also provide "supervision and in-service training to all noncore staff." *Id.* § 429.439(B).

b. According to relators' second amended complaint, their daughter, Rivera, first received counseling services from the Lawrence clinic in 2004, after experiencing behavioral problems at her middle school. 1JA16 (Compl. ¶ 23). Rivera then returned to the Lawrence clinic for additional counseling in 2008, after her school observed that she was having difficulty interacting with other students. 1JA16 (Compl. ¶ 25).

According to the complaint, relators were dissatisfied with the first two counselors assigned to their daughter. 1JA17-20 (Compl. ¶¶ 30, 37-39, 53, 56-57). After relators conferred with the Lawrence clinic's clinical director, Edward Keohan, Rivera was reassigned to another staff member. 1JA21 (Compl. ¶ 64). That staff member, who represented herself as a "psychologist," later diagnosed Rivera with bipolar disorder. 1JA21-22 (Compl. ¶¶ 65, 71). Although this staff member possessed a doctorate in psychology, according to the complaint she had earned the degree from an online university not recognized by the Massachusetts Board of Licensure, and the Commonwealth had rejected her application to become a licensed psychologist. 1JA21 (Compl. ¶¶ 67-69).

In May 2009, Rivera again experienced behavioral difficulties at school, and her school determined

that she would not be permitted to return until she had been seen by a psychiatrist. 1JA23 (Compl. ¶¶ 79-80). Rivera was referred to another staff member at the Lawrence clinic, whom relators understood to be a psychiatrist, but who was in fact a nurse practitioner, according to the complaint. 1JA23 (Compl. ¶¶ 82-84). The nurse practitioner prescribed Trileptal to treat Rivera's condition. 1JA23 (Compl. ¶ 85). According to relators' complaint, however, a nurse may prescribe psychiatric medication only when supervised by a board-certified psychiatrist. 1JA24 (Compl. ¶ 86). Relators allege that the only psychiatrist employed by the Lawrence clinic was not board certified and had not supervised the nurse who prescribed the medication to Rivera. 1JA24 (Compl. ¶ 87).

Relators allege that Rivera experienced an adverse reaction to Trileptal and decided to discontinue taking the medication after only a few days. 1JA24 (Compl. ¶¶ 88, 90). Several days after discontinuing the medication, she suffered a seizure and was hospitalized. 1JA24 (Compl. ¶ 92). Rivera continued to receive counseling at the Lawrence clinic during the summer and fall of 2009, but in October 2009 she suffered another seizure and died. 1JA27 (Compl. ¶¶ 113-114).

Following Rivera's death, relators filed administrative complaints with several state agencies, including the Disabled Persons Protection Committee (DPPC), the Division of Professional Licensure (DPL), and the Department of Public Health (DPH). 1JA28-44 (Compl. ¶¶ 122-197). According to a report summarizing the DPPC's investigation, attached by relators to their complaint as an exhibit, the DPPC

found that, although seizures are a potential complication from Trileptal withdrawal, there was insufficient evidence to conclude that Rivera's prescription had led to her death. 2JA171. The DPPC thus concluded that Rivera had not been subjected to "abuse" by a caregiver, as relators had alleged. 2JA165-166.

Following an investigation by the DPL, the Lawrence clinic's clinical director, Keohan, entered into a consent decree in which he acknowledged that sufficient facts existed to support a conclusion that he had authorized and supervised one of Rivera's initial counselors in the unlicensed practice of social work. 2JA198-201. Keohan agreed that his license to practice social work would be subjected to a two-year period of supervised probation, during which he would be supervised by an independent monitor. *Ibid*. A separate investigation of the staff member who had held herself out as a psychologist was also resolved by consent decree. 2JA203-205. That staff member agreed to pay a civil penalty of $1,000 and to refrain from holding herself out as a licensed psychologist. *Ibid*.

A DPH investigation of the Lawrence clinic, the results of which were attached to relators' complaint, found deficiencies in the clinic's operations, including violations of DPH regulations governing the required credentials for clinic staff and the supervision of staff members. 2JA219-225. The DPH accepted a "Plan of Correction" for the Lawrence clinic, which contained steps to address each regulatory deficiency

noted in the report. 2JA21-24.[3] The plan required the clinic to improve its documentation of supervision, to provide "1 hour of individual supervision" to clinicians who were not licensed to practice independently, and to provide all clinicians with "access to weekly group supervision." 2JA24. Relators' complaint does not allege that the MassHealth program ever sought to withhold or recover amounts paid to petitioner as a consequence of any regulatory violations.

c. In 2011, relators brought this *qui tam* action against petitioner. Relators alleged that petitioner had violated the FCA, and parallel state-law provisions,[4] by seeking reimbursement for services provided even though (i) the four staff members who had provided services to Rivera, and other unnamed staff members, had not been properly supervised as required by MassHealth regulations, 1JA44-56 (Compl. ¶¶ 198-275); and (ii) the Lawrence clinic was in violation of staffing regulations, because it had not employed a board-certified psychiatrist and a licensed psychologist, 1JA56-59 (Compl. ¶¶ 276-292).

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[3] The portion of the DPH report documenting the Lawrence clinic's plan of correction was included as part of an exhibit attached to relators' first amended complaint (2JA1-24), but omitted from the version of that exhibit attached to relators' second amended complaint (2JA206-225).

[4] As the court of appeals observed, the federal FCA and its Massachusetts counterpart are similar, and "the state statute[ ] may be construed consistently with the federal act." Pet. App. 17 n.13 (internal quotation marks omitted).

Relators alleged that the Lawrence clinic had misrepresented its compliance with those regulations simply by submitting claims for reimbursement to MassHealth. Relators did not assert that the clinic had expressly misrepresented its compliance with any regulations.

After reviewing relators' complaint, the United States and the Commonwealth of Massachusetts declined to intervene. Pet. App. 9 n.8, 32. Relators twice amended their complaint and proceeded with the litigation.

The district court dismissed the complaint. Pet. App. 25-53. Recognizing that "not every regulatory violation gives rise to a potential FCA action," the court observed that "[t]he 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." Pet. App. 37. The district court acknowledged that, under First Circuit precedent, an FCA claim could proceed on the theory that submission of a claim for payment impliedly represents compliance with statutory, regulatory, or contractual requirements. The court held, however, that the plaintiff must identify a violation of a "precondition to payment" to establish falsity. Pet. App. 38. "Violations of only a condition of participation will not suffice." *Ibid.*

Applying that standard, the court held that relators had failed to identify any violations of preconditions to payment. It noted that, with one exception, the MassHealth regulations within Chapter 429.000 that relators had invoked in their

complaint and in their opposition to petitioner's motion to dismiss did not state that compliance was a precondition to reimbursement. As a consequence, the district court explained, the introductory material in 130 Mass. Code Regs. § 429.401 implied that they were simply "requirements for participation of mental health centers in MassHealth," not preconditions to payment. Pet. App. 39.

The exception was Section 429.439, which (as noted above) sets forth rules governing satellite programs of mental health centers and states that "[s]ervices provided by a satellite program are reimbursable only if the program meets the standards provided below." 130 Mass. Code Regs. § 429.439. Although the court noted that this regulation did supply certain preconditions to reimbursement, Pet. App. 43, it concluded that relators had not plausibly alleged any violation of it. The court held that relators had not stated any violations of subsections (A), (C), and (D), because those subsections address supervision and management of the satellite program by its parent center, and relators' allegations addressed only inadequate supervision *within* the Lawrence clinic itself. Pet. App. 43-44. As for subsection (B), the court concluded that relators had failed to allege that the Lawrence clinic was subject to this provision, because subsection (B) applies only to "autonomous" satellite programs and relators' complaint did not allege whether the Lawrence clinic was autonomous from or dependent on its parent center. Pet. App. 44.

The district court then rejected relators' reliance on regulations promulgated by the DPH and by the Board of Registration in Medicine. None of the cited

regulations related to payment under the MassHealth program. Pet. App. 45-47.

Although the district court stated that relators' allegations "raise[d] serious questions about the quality of care provided to" Rivera, it concluded that "the False Claims Act is not the vehicle to explore those questions." Pet. App. 53. "[T]he [False Claims] Act * * * [is] directed at materially false statements presented to obtain government reimbursement," the district court explained. *Ibid.* Because relators had not identified any precondition to reimbursement that petitioner had allegedly violated, they had not "made adequate allegations regarding such statements." *Ibid.*

d. The court of appeals reversed in relevant part. Pet. App. 1-24. It explained that other courts have generally distinguished between submissions "that are factually false and those that are legally false," and have distinguished within the latter category between claims based on "either 'implied' or 'express' certification of compliance with conditions of payment." Pet. App. 12. But the First Circuit's own recent precedents had "eschewed" those distinctions. *Ibid.* The court opined that those distinctions "'create artificial barriers that obscure and distort [the statute's] requirements.'" Pet. App. 12-13 (quoting *United States ex rel. Hutcheson* v. *Blackstone Med., Inc.*, 647 F.3d 377, 385 (1st Cir. 2011)). Applying its self-consciously "broad view of what may constitute a false or fraudulent statement," the court of appeals "ask[ed] simply whether the defendant, in submitting a claim for reimbursement, knowingly misrepresented compliance

with a material precondition of payment." Pet. App. 13.

The court of appeals also stated that, under circuit precedent, preconditions to payment that may trigger liability under the FCA "may be found in sources such as statutes, regulations, and contracts," and "need not be 'expressly designated.'" Pet. App. 13 (quoting *Hutcheson*, 647 F.3d at 387-388). Instead, "the question whether a given requirement constitutes a precondition to payment is a 'fact-intensive and context-specific inquiry.'" *Ibid.* (quoting *New York* v. *Amgen Inc.*, 652 F.3d 103, 111 (1st Cir. 2011)).

The court held that relators' complaint adequately alleged the Lawrence clinic's noncompliance with preconditions to payment. The court of appeals did not disagree with the district court's holding that, with the exception of Section 429.439, none of the regulations cited by relators made compliance a condition of payment. Pet. App. 15. Nor did the court of appeals take issue with the district court's conclusion that relators had not plausibly alleged a violation of Section 429.439's standard requiring autonomous satellite programs to supervise their noncore staff members.

Instead, the court of appeals faulted the district for "overlook[ing]," Pet. App. 16, a different regulation that neither relators nor the Commonwealth, as *amicus curiae*, had ever invoked: 130 Mass. Code Regs. § 429.423(B)(2). According to the court of appeals, that provision is referenced in Section 429.439(C), which states 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, the first of which sets forth, in clear terms, the qualifications 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).

Relators did not allege, and the court of appeals did not conclude, that the clinical director of the Lawrence clinic failed to meet any of the requirements set forth in paragraph (1). Instead, the court of appeals invoked Section 429.423(B)'s second paragraph, which provides that "[t]he 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).

In the court of appeals' view, because Section 429.439 conditions payment on compliance with "the standards described below," and because Section 429.439(C) states that a clinical director must satisfy "the requirements in [Section] 429.423(B)," it follows that *every* part of Section 429.423(B) is a material precondition to payment. Pet. App. 16. In other words, the court concluded, MassHealth regulations make "the clinical director's fulfillment of his or her regulatory duties"—including the list of job responsibilities of a clinical director—a precondition to payment, apparently for all services provided by the satellite clinic. *Ibid.*

With respect to relators' claims that petitioner had submitted fraudulent reimbursement requests for services provided by staff members who allegedly did not receive adequate supervision, the court of appeals noted that Section 429.423(B)(2)(c) makes the clinical director responsible for "overall supervision of staff performance." Pet. App. 16. Based on

its conclusion that proper performance of each of the clinical director's responsibilities constituted a precondition to payment, the court held that relators had adequately pleaded that petitioner's "claims for reimbursement * * * were false within the meaning of the Act, in that they misrepresented compliance with a condition of payment, i.e., proper supervision." Pet. App. 17.

Although the court of appeals used the language of "misrepresent[ation]," it acknowledged that relators had not alleged that petitioner "explicitly represented that it was in compliance with conditions of payment when it sought reimbursement from MassHealth." Pet. App. 17-18 n.4. The court explained, however, that it had "not required such 'express certification' in order to state a claim under the FCA." *Ibid.* Instead, according to the court, "each time it submitted a claim, [petitioner] implicitly communicated that it had conformed to the relevant program requirements, such that it was entitled to payments." *Ibid.*

The court of appeals also held that relators had adequately alleged scienter in connection with their inadequate-supervision claims, relying on the complaint's quotation from DPH's interview of Keohan, the Lawrence clinic's clinical director. In that interview, Keohan acknowledged that, until recently, he had had been "unaware that supervision was required to be provided on a regular and ongoing bas[i]s, or that the supervision meetings needed to be documented." Pet. App. 18. In the court's view, Keohan's statement, standing alone, "more than suffice[d] to establish that [petitioner] acted in reckless disregard or deliberate ignorance of the

falsity of the information contained in the claims." *Ibid*. (citing 31 U.S.C. § 3729(b)(1)(A)). In other words, the knowledge element, which likely would have been satisfied if Keohan had known of the job-responsibility-turned-requirement, was also satisfied precisely because he did not know about it.

The court of appeals then turned to relators' separate claim that petitioner had violated the FCA by submitting claims for reimbursement while in violation of state regulations requiring mental-health clinics to employ at least one board-certified psychiatrist. Pet. App. 20-22. None of the regulations that relators cited as establishing this staffing obligation conditioned reimbursement on compliance. See 105 Mass. Code Regs. § 140.530(C)(1)(a); 130 Mass. Code Regs. § 429.422; *id.* § 429.424. But the court of appeals nonetheless reasoned that, because Section 429.423(B)(2)(e) makes the clinical director "accountab[le] for employing adequate psychiatric staff to meet the psychopharmalogical needs of clients," *id.* § 429.423(B)(2)(e), and because it had concluded that "claims are reimbursable only if the clinical director fulfills the assigned duties," Pet. App. 21 (citing 130 Mass. Code Regs. § 429.439(C)), the "failure to maintain a properly licensed psychiatrist on staff constituted noncompliance with a material condition of payment," Pet. App. 21-22.

The court of appeals reached that conclusion even though the regulation it read as imposing the duty to keep one board-certified psychiatrist on staff was promulgated by the DPH, not by MassHealth. See Pet. App. 20 n.15 (relying on 105 Mass. Code Regs. § 140.530). Nothing in MassHealth's regulations cross-referenced the DPH's rule or otherwise sug-

gested that it would supply the standard for determining whether a clinic had employed "adequate" psychiatric staff for purposes of the MassHealth program.

In fact, as the court of appeals came close to acknowledging, see Pet. App. 20 n.15, the Massachusetts regulations governing clinic staffing were impossible to reconcile. Section 429.422 provides that "mental health centers" must employ at least one psychiatrist. See 130 Mass. Code Regs. § 429.422(A). A "mental health center" is defined as "an entity that delivers a comprehensive group of diagnostic and psychotherapeutic treatment services * * * by an interdisciplinary team under the medical direction of a psychiatrist," 130 Mass. Code Regs. § 429.402, a concept that appears to refer to an entity comprising *both* the parent center and the satellite locations. See also *id.* § 429.402 (defining "Parent Center" as "the central location of the mental health center" and defining "Autonomous Satellite Program" and "Dependent Satellite Program" as "a mental health center program"). On this understanding, a satellite clinic that does not employ its own psychiatrist is not out of compliance with the staffing regulation so long as the broader mental health center has a psychiatrist on staff.

On the other hand, as the court of appeals put it, DPH regulations "suggest something else." Pet. App. 21 n.15. One regulation promulgated by DPH states that every mental health clinic must employ a board-certified psychiatrist. See 105 Mass. Code Regs. § 140.530(C)(1)(a). A separate regulation provides that a satellite clinic "must meet [this requirement] independently of its parent clinic." *Id.* § 140.330. In

resolving the tension between the MassHealth and DPH regulations—and concluding that relators had adequately alleged that petitioner fraudulently (albeit impliedly) certified compliance with the rule "suggest[ed]" by the DPH's staffing regulation—the court afforded "controlling weight" to the DPH's conclusion, announced in its after-the-fact investigation prompted by relators' administrative complaints, that the Lawrence clinic had violated Section 140.530. See Pet. App. 21 n.15.

The court of appeals affirmed the dismissal of claims premised on the Lawrence clinic's alleged failure to employ a licensed psychologist. Pet. App. 22 n.16. The court explained that the "regulations do not mandate that a psychologist be on staff at all times," and therefore held that relators' allegation that the staff member who held herself out as a psychologist was not licensed did not establish any regulatory violation. *Ibid*.

The court of appeals denied rehearing and rehearing en banc. Pet. App. 54-55.

SUMMARY OF THE ARGUMENT

I. The False Claims Act does not permit liability to be imposed on the basis of the implied-certification theory, under which claims that contain no affirmative misstatements are deemed to be "false or fraudulent" because the claimant does not disclose that it has violated a requirement of the relevant federal program or contract.

A. The implied-certification theory cannot be squared with the text of 31 U.S.C. § 3729(a)(1)(A). A "claim for payment" is not "false" within the meaning of the FCA if it does not contain an affirmative

misstatement, and such a claim cannot be deemed "fraudulent" based on a contractor's failure to disclose its violation of a legal requirement unless the contractor is under a duty to disclose the noncompliance. Section 3729(a)(1)(A) creates no such duty, and background common-law principles do not support the imposition of such a duty in this context.

B. Policy considerations provide no basis to expand liability under the FCA beyond its textual limitations by adopting the implied-certification theory. This Court has explained that the Act "reach[es] all types of *fraud*, without qualification, that might result in financial loss to the Government." *United States* v. *Neifert-White Co.*, 390 U.S. 228, 232 (1968) (emphasis added). But the implied-certification theory would extend liability well beyond traditional conceptions of fraud, making the FCA a blunt instrument to penalize noncompliance with regulatory and contractual requirements.

Likewise, references to the scope of liability under the FCA in the legislative history that accompanied Congress's 1986 amendments to the Act provide no indication that Congress intended to authorize the implied-certification theory. Reinforcing the lesson from statutory text and legislative history, there are sound policy reasons for rejecting the theory.

II. If the implied-certification theory is to be adopted at all, its application is appropriately limited to circumstances in which a contractor has violated a statutory, regulatory, or contractual provision that is expressly designated as a precondition to payment.

A. 1. Because the premise of implied-certification liability is that the act of submitting a claim for payment may certify compliance with underlying legal requirements, the theory can apply only when those requirements are preconditions to payment. Without a direct link between compliance and payment, there is no logical basis to treat the submission of a claim as certification of compliance. And, if the condition-of-payment requirement is to have any meaningful effect, the conditions must be expressly designated as prerequisites to payment. Otherwise, participants in federal programs and contractors will face liability for any violation that a court might later determine was "material" to the government's payment decision. That is deeply unfair, and it is implausible to treat a contractor's claim as an implicit certification that all such conditions have been satisfied.

2. The FCA's scienter element reinforces the requirement that conditions of payment must be expressly stated. The implied-certification theory requires that the program participant or contractor have knowledge that the underlying legal requirement was violated and knowledge that compliance was a condition of payment. Even the FCA's most expansive conception of scienter—reckless disregard—*precludes* liability unless a defendant acts under an "objectively unreasonable" understanding of the applicable legal requirements. *Safeco Ins. Co. of America* v. *Burr*, 551 U.S. 47, 69 (2007); see also *United States ex rel. Purcell* v. *MWI Corp.*, 807 F.3d 281, 287-288 (D.C. Cir. 2015). When a legal requirement is not expressly designated as a condition of payment, it is not "objectively unreasonable" to conclude that it is not one.

3. If a claim can proceed based on alleged violation of a requirement that is not expressly designated as a condition of payment, courts will not reliably differentiate between conditions of payment and conditions of participation in government programs. Leaving that crucial distinction to after-the-fact advocacy by self-interested actors will threaten boundless liability for healthcare providers like petitioner, and others involved in federal programs and contracts. It will also allow private *qui tam* relators to interfere with the government's more finely calibrated measures for policing compliance with legal requirements. Indeed, that is what relators attempt to do in this case, where multiple state agencies reviewed the alleged regulatory noncompliance and took the corrective action they deemed appropriate—action that bears no resemblance to the treble damages and penalties that relators seek here.

B. Proponents of the implied-certification theory often suggest that the FCA's materiality and scienter elements will protect against abusive FCA claims, but such assurances are hollow. In practice, those elements are often ill suited for resolution on a motion to dismiss. As a practical matter, the extraordinary cost of discovery in FCA litigation and the risk of treble damages, per-claim civil penalties, and the opprobrium of being said to have "defrauded" the government place strong pressure to settle on even defendants with meritorious defenses.

III. The judgment of the court of appeals should be reversed if the Court adopts petitioner's position on either of the two questions presented.

A. The court of appeals' decision rests on the premise that submission of a claim impliedly certifies

compliance with underlying legal requirements. If the Court rejects that premise, the judgment must be reversed.

B. The court of appeals' decision also cannot be squared with a rule requiring conditions of payment to be expressly designated as such to support a claim under the implied-certification theory. None of the Massachusetts regulations cited by the court of appeals expressly tied reimbursement to compliance with the supervision and staffing requirements that relators allege were violated.

ARGUMENT

This Court has never adopted or endorsed the theory of "implied false certification." The Court should now reject that theory altogether. "[A]llowing 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 contrary to the clear language of the statute * * *.*" 1 John T. Boese, *Civil False Claims and* Qui Tam *Actions* § 2.03[G][1][a], at 2-191 (4th ed. 2011 & Supp. 2016-1) (emphasis added). The proper solution to the fundamental problems with the implied-certification theory—chiefly, the lack of statutory authority and over-enforcement of regulatory norms—is to reject that theory completely.

The second-best solution, adopted by many courts but rejected by the First Circuit below, is to cabin the theory so that it is applied "only where Congress or an agency acting under appropriately delegated authority has, in effect, made an explicit materiality determination and has expressly conditioned payment of a claim on statutory or regulatory compliance." 1 Boese, *supra*, § 2.03[G][1][a], at 2-197 (citing *Mikes* v. *Straus*, 274 F.3d 687, 699-700 (2d Cir. 2001)). That "requirement properly forces the government to formally identify in advance of a claim submission those requirements that are material to its payment decision." *Ibid.*

If this Court either rejects the implied-certification theory or limits it to requirements identified in advance as conditions of payment, the judgment of the First Circuit should be reversed and the complaint dismissed.

I. The False Claims Act Does Not Impose Liability On The Basis Of "Implied Certifications" Of Compliance With Statutory, Regulatory, Or Contractual Requirements

Liability may be imposed under Section 3729(a)(1)(A) only on the basis of a "false or fraudulent claim for payment." The court of appeals concluded that a claim that itself contains no false representations may nonetheless be "false or fraudulent" on the theory that, just by submitting a claim, the claimant "implicitly communicate[s] that it ha[s] conformed to the relevant program requirements." Pet. App. 17 n.14. This theory of falsity—based on the notion of "implied certification"—finds no

purchase in the text or history of the FCA and is unsupported by considerations of statutory purpose.

A. Violations Of Statutory, Regulatory, Or Contractual Requirements Do Not Render A Claim For Payment "False Or Fraudulent"

Interpretation of the FCA "start[s], as always, with the language of the statute." *Allison Engine Co.* v. *United States ex rel. Sanders*, 553 U.S. 662, 668 (2008) (quoting *Williams* v. *Taylor*, 529 U.S. 420, 431 (2000)). Section 3729(a)(1)(A) imposes liability on any person who "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval." 31 U.S.C. § 3729(a)(1)(A). The implied-certification theory imposes liability for "claims" that are neither "false" nor "fraudulent" and thus sweeps well beyond the statute's scope.

The FCA's prohibition of "false" claims corresponds to what a number of lower courts have labeled "factual falsity"—*i.e.*, claims that incorrectly describe the goods or services provided, or seek reimbursement for goods or services that were not provided. See, *e.g.*, *Mikes*, 274 F.3d at 697. It may also reach claims that are accompanied by an affirmative, false representation regarding the claimant's compliance with one or more underlying statutory, regulatory, or contractual duties that are preconditions to payment by the government—that is, so-called express false certifications. See, *e.g.*, *id.* at 697-698. In each instance, the invoice (*i.e.*, "claim") is itself false and therefore actionable.

By contrast, a claim that accurately describes the goods or services for which payment is sought, and

contains no false representations, is not "false." The essence of "falsity" is whether a statement made is incorrect, not whether a statement that *was not* made would have been incorrect. The implied-certification theory thus cannot rest on the ordinary meaning of "false." See *United States ex rel. Steury* v. *Cardinal Health, Inc.*, 735 F.3d 202, 209-210 (5th Cir. 2013) (Higginson, J., concurring) ("I would favor restoring Congress's statutory distinction between falsity and fraud, and using traditional, common-sense understandings of those terms to decide whether [a plaintiff] state[s] a claim under the FCA. * * * Just as an insufficient funds check alone makes no falsifiable assertion, neither does an unadorned invoice contain a false claim."); see also *Williams* v. *United States,* 458 U.S. 279, 284-285 (1982).

The FCA's prohibition on "fraudulent" claims is likewise defined by common legal understanding. "It is a well-established rule of construction that '[w]here Congress uses terms that have accumulated settled meaning under * * * the common law, a court must infer, unless the statute otherwise dictates, that Congress means to incorporate the established meaning of these terms.'" *Neder* v. *United States*, 527 U.S. 1, 23 (1999) (quoting *Nationwide Mut. Ins. Co.* v. *Darden*, 503 U.S. 318, 322 (1992)); see also, *e.g.*, *Standard Oil Co.* v. *United States*, 221 U.S. 1, 59 (1911) ("[W]here words are employed in a statute which had at the time a well-known meaning at common law or in the law of this country, they are presumed to have been used in that sense * * *.").

As this Court has held, "actionable 'fraud'" has long "had a well-settled meaning at common law." *Neder*, 527 U.S. at 22. A core component of that

common-law understanding is the principle that, "[w]hen an allegation of fraud is based upon nondisclosure, there can be no fraud absent a duty to speak." *Chiarella* v. *United States*, 445 U.S. 222, 235 (1980); see also, *e.g.*, Restatement (Second) of Torts § 551(1) (1977) (limiting liability for nondisclosure to situations in which one "is under a duty to [another] to exercise reasonable care to disclose the matter in question"); 3 Dan B. Dobbs *et al.*, *The Law of Torts* § 682, at 701-702 (2d ed. 2011) (stating the "traditional rule" that, "[w]hen it comes to mere nondisclosure without active concealment, * * * the bargainer is not ordinarily obliged to make affirmative revelations of known material facts").

Section 3729(a)(1)(A) itself does not impose any duty to disclose statutory, regulatory, or contractual violations in connection with submitting a claim for payment. To the contrary, because Congress used the word "fraudulent" and thus incorporated that term's common-law definition, liability may be imposed under the FCA on the basis of nondisclosure only where some *other* source of law imposes a duty of disclosure.

No other source of law imposes such a general duty in connection with the submission of a claim for payment. Certainly government program participants and contractors do not, simply by virtue of submitting claims, occupy a "fiduciary or other similar relation of trust" with the federal government. Restatement (Second) of Torts § 551(2)(a). They accordingly do not take on the special duties of disclosure that attend such a role.

The common law has never understood the act of seeking payment under a contract as giving rise to a duty of disclosure. Instead, cognizant of the risk of "turning every breach of contract into an actionable claim for fraud," *Richmond Metro. Auth.* v. *McDevitt Street Bovis, Inc.,* 507 S.E.2d 344, 348 (Va. 1998), courts have held that "failing to disclose a breach of promise does not transform a contract action into one for fraud," *Compania Sud-Americana de Vapores, S.A.* v. *IBJ Schroder Bank & Trust Co.*, 785 F. Supp. 411, 423 (S.D.N.Y. 1992) (applying New York law); cf. *Myklatun* v. *Flotek Indus., Inc.*, 734 F.3d 1230, 1235-1236 (10th Cir. 2013) (holding that, as a general matter, "the proper remedy for a breach of contract will be found in a breach of contract claim, not in a claim of fraud based on the breaching party's failure to disclose its potential future breach"). That principle, developed outside the FCA context, appropriately applies in FCA cases as well because of the statute's use of the common-law concept of "fraudulent" action. Unsurprisingly, the fundamental principle that contract actions should not be alchemized into fraud actions is recognized in many FCA cases (although not all courts have carried it far enough). *E.g.*, *United States* v. *Sanford-Brown, Ltd.*, 788 F.3d 696, 710 (7th Cir. 2015); *United States* v. *Science Applications Int'l Corp.*, 626 F.3d 1257, 1271 (D.C. Cir. 2010) (*SAIC*); *United States ex rel. Steury* v. *Cardinal Health, Inc.*, 625 F.3d 262, 268 (5th Cir. 2010) (*Steury I*); *United States ex rel. Wilson* v. *Kellogg, Brown & Root, Inc.*, 525 F.3d 370, 378 (4th

Cir. 2008); *United States* v. *Southland Mgmt. Corp.*, 326 F.3d 669, 676 (5th Cir. 2003) (en banc).[5]

A request for payment under a government program or contract thus does not in itself provide an assurance that the claimant has complied with the terms of that program. To hold otherwise would effectively impose a fiduciary obligation on every individual or business that submits claims to the government, or causes claims to be submitted. There is no basis in the FCA itself or in pertinent background legal principles for that extraordinary result.

B. Considerations Of Statutory Purpose Do Not Warrant Adoption Of The Implied-False-Certification Theory

Lacking a foothold in the statute's text, the lower courts that have created and defended the implied-certification theory have retreated to broad considerations of statutory purpose. They have invoked this Court's statement that the FCA "was intended to reach all types of fraud, without qualification, that might result in financial loss to the Government,"

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[5] The principle has also been recognized under the federal mail, wire, and bank fraud statutes, see 18 U.S.C. §§ 1341, 1343, 1344—three statutes under which a request for continued performance while in breach of a contract does not constitute fraud. See *United States* v. *Steffen*, 687 F.3d 1104, 1116-1117 (8th Cir. 2012) (dismissing indictment because defendant's request for advance on a loan while in breach of loan agreement did not "implicitly represent[] that all of the representations and warranties in the security and loan agreements were true and correct in all material respects").

United States v. *Neifert-White Co.*, 390 U.S. 228, 232 (1968), as well as legislative history accompanying the False Claims Amendments Act of 1986, Pub. L. No. 99-562, 100 Stat. 3154. But such amorphous considerations do not actually support the implied-certification theory, and thus are a particularly tenuous basis on which to expand the scope of an "essentially punitive" statute. *Vermont Agency*, 529 U.S. at 784.

1. Far from supporting the implied-certification theory, this Court's statement in *Neifert-White Co.* counsels against it. First, the case did not involve implied fraud or falsity at all, but rather considered whether an explicitly false application for a federal loan was within the FCA's ambit. The defendant had "prepared invoices in which the purchase price [for grain storage bins] was deliberately overstated," and submitted the invoices with the "purpose [of] *** induc[ing] the [government] to extend loans." *Neifert-White*, 390 U.S. at 230. Second, the Court's statement was expressly limited to "all types of *fraud*." *Id.* at 232 (emphasis added). As explained at pp. 30-33 above, the well-established meaning of "fraud" at common law does not encompass a request for payment that contains no false information, and is alleged to be false only because the claimant has breached a statutory, regulatory, or contractual provision.

Thus, although the Court has refused to adopt a "rigid" or "restrictive" reading of the FCA, *Neifert-White*, 390 U.S. at 232, the FCA must be confined to conduct that would be recognized as actual "fraud." See also, *e.g.*, *Rainwater* v. *United States*, 356 U.S. 590, 592, (1958) ("[T]he objective of Congress was

broadly to protect the funds and property of the Government from *fraudulent* claims * * *." (emphasis added)). As this Court observed in another context in which statutory breadth was said to justify imposing liability beyond traditional conceptions of fraud, "Section 10(b) [of the Securities Exchange Act of 1934] is aptly described as a catchall provision, *but what it catches must be fraud*." *Chiarella*, 445 U.S. at 234-235 (emphasis added).

2. The legislative history of the False Claims Amendments Act of 1986, Pub. L. No. 99-562, 100 Stat. 3154, also cannot extend the statute beyond its plain textual limits—that is, beyond what the common law would have recognized as "fraud." The accompanying Senate Report stated that "[t]he False Claims Act is intended to reach all fraudulent attempts to cause the Government to pay out sums of money or to deliver property or services." S. Rep. 345, 99th Cong., 2d Sess. 9 (1986) (*1986 Senate Report*). This again confirms Congress's recognition that the FCA is limited to fraudulent conduct. That is, the fact that Congress intended to reach "all fraudulent attempts" still requires a court to determine whether a claim is "fraudulent." Proponents of the implied-certification theory, however, simply skip that step: Because the FCA reaches all types of fraud, they say, implied certification must be fraud. That is an obvious logical fallacy.

The *1986 Senate Report* also states that "a false claim may take many forms, the most common being a claim for goods or services not provided, or provided in violation of contract terms, specifications, statute, or regulations." *1986 Senate Report* 9. But that language does not lend support to the implied-

certification theory, because it does not suggest that all goods or services provided in violation of such underlying legal requirements—*regardless of what is stated in the claim for payment*—are considered "false or fraudulent" within the meaning of the FCA. Claimants under federal programs and contracts often must explicitly certify compliance with statutory, regulatory, or contractual requirements as part of a claim for payment.[6] A false *certification of compliance* may of course render a claim "false or fraudulent." That is what most courts call the "express certification" theory of FCA liability. It is very different from saying that a claim for payment for services rendered becomes "false or fraudulent" *just because* there has been some violation of some requirement, about which the billing party has said nothing.

Moreover, none of the three cases cited in support of this passage in the *1986 Senate Report* relied on anything like a theory of implied certification. One

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[6] See, *e.g.*, *United States ex rel. Riley* v. *St. Luke's Episcopal Hosp.*, 355 F.3d 370, 376 & n.6 (5th Cir. 2004) (addressing Medicare reimbursement forms that require an express certification "that the services shown on this form were medically indicated and necessary for the health of the patient"); *Southland*, 326 F.3d at 672 (addressing form voucher under housing subsidy program that required owner to certify, among other things, that "the dwelling units are in Decent, Safe, and Sanitary condition"); *United States ex rel. Howard* v. *Lockheed Martin Corp.*, 14 F. Supp. 3d 982, 989 (S.D. Ohio 2014) (noting that payment requests contained "certification that the costs [for which reimbursement was sought] were applicable, allocable, and reasonable").

cited decision, *United States* v. *Bornstein*, 423 U.S. 303 (1976), involved a subcontractor that had delivered noncompliant electron tubes, but had "falsely marked" the tubes to indicate that they complied with contractual specifications. *Id.* at 307. That sort of *active concealment* of the contractor's noncompliance fits comfortably within the common-law understanding of fraud. See Restatement (Second) of Torts § 550. The same principle also explains another cited decision, *United States* v. *National Wholesalers*, 236 F.2d 944 (9th Cir. 1956), which involved a contractor that had "deliberate[ly] mislabel[ed]" motor vehicle parts that it delivered to the government, in order to mask the parts' non-compliance with contractual requirements. *Id.* at 950. Both cases involved factually false statements in a quite ordinary sense. In neither case was a theory of implied certification necessary to bring the defendants' conduct within the well-established scope of actionable fraud at common law.

The third case cited by the *1986 Senate Report*, *Henry* v. *United States*, 424 F.2d 677 (5th Cir. 1970), also does not support the implied-certification theory. There, a contractor had purported to deliver pine oil disinfectant to the government under a contract that specified the minimum pine oil content. *Id.* at 678. The material delivered failed to meet the required specifications, by a wide margin, such that the government determined that it was "without value for its purposes." *Id.* at 678 n.1. Thus, the decision does not apply anything like an implied-certification theory of falsity. Instead, the decision applies the principle, adopted more recently by some lower courts, that providing worthless goods or services to the government may render a request for

payment *factually* false, because it is as if the contractor provided *no goods or services at all*, and thus failed to deliver what it said it did. See, *e.g.*, *Mikes*, 274 F.3d at 702 ("An allegation that defendants violated the Act by submitting claims for worthless services is not predicated upon the false certification theory."); *United States ex rel. Lee* v. *SmithKline Beecham, Inc.*, 245 F.3d 1048, 1053 (9th Cir. 2001) ("In an appropriate case, knowingly billing for worthless services or recklessly doing so with deliberate ignorance may be actionable under § 3729, regardless of any false certification conduct."); cf. *Strickland* v. *Washington*, 466 U.S. 668, 686 (1984) (providing a lawyer so ineffective as to fall below minimum standards of professional conduct deemed constitutionally equivalent to not providing the assistance of counsel at all).

Thus, the *1986 Senate Report* reflects the view that, *in some circumstances such as express certification or the delivery of worthless goods*, a claim under the FCA may involve a contractor's violation of underlying legal requirements. But it does not support the notion that any claim for payment impliedly represents that the contractor has complied with statutory, regulatory, and contractual duties. It accordingly provides no basis for adopting the implied-certification theory and massively expanding the reach of a statute that imposes draconian penalties.

3. Abundant reasons support Congress's decision to limit liability to truly "false or fraudulent" claims.

For starters, imposing liability on the basis of *implied* certifications would drain almost all practical significance from the government's decision to re-

quire *express* certifications of compliance. The government routinely requires such certifications, in a variety of contexts. See p. 36 & note 6, *supra*. If the act of submitting a claim for payment is understood as certifying compliance with every jot and tittle of statutory, regulatory, and contractual obligations, however, then those express-certification requirements are essentially surplusage. A theory of falsity under the FCA that renders this commonplace feature of government contracting a dead letter has little to recommend it.

Requiring the government to identify, in advance, those underlying legal duties with which a claimant must expressly certify compliance also has the salutary effect of providing clear notice of the requirements for seeking payment from the government and advising claimants precisely what they are representing to be true at the time of billing. That notice, in turn, allows program participants and contractors to focus their compliance efforts on those particular priority areas that the government has identified. If the FCA is read to impose massive liability on an implied-certification theory, however, then focusing compliance efforts in this manner becomes impossible, because a claimant could be subject to punitive liability for *any* underlying legal duties that a court ultimately determines are within the scope of an implied certification.

Not imposing FCA liability on the basis of implied certification is also consistent with considerations of basic fairness. No matter how narrowly circumscribed, "the implied certification theory has the effect of putting words—false ones, at that—into the defendant's mouth, and then penalizing the defen-

dant for those alleged falsities." 1 Boese, *supra*, § 2.03[G][2], at 2-207.

Those who do business with the government—and health care providers like petitioner, in particular—face duties that are voluminous and sometimes difficult to decipher. "[A]nyone examining Medicare regulations would conclude that they are so complicated that the best intentioned plan participant could make errors in attempting to comply with them." *United States ex rel. Wilkins* v. *United Health Group, Inc.*, 659 F.3d 295, 310 (3d Cir. 2011); see also, *e.g.*, *United States ex rel. Drakeford* v. *Tuomey*, 792 F.3d 364, 390, 395 (4th Cir. 2015) (Wynn, J., concurring) (referring to the "impenetrably complex set of laws and regulations" governing the Medicare program, and characterizing the Stark Law, in particular, as a "booby trap" for "well-intentioned health care providers").

A theory making every "knowing" and "material" breach of a statutory, regulatory, or contractual requirement into an implied "fraud" when payment is sought has enormous implications. In *United States* v. *Education Management Corp.*, 871 F. Supp. 2d 433 (W.D. Pa. 2012), for example, the government alleged that the defendant schools' requests for federal student aid funding were impliedly false because the schools had violated a statutory prohibition on the payment of incentive compensation to recruiters. See *id.* at 440-442. The government alleged that the defendants had wrongfully obtained more than *$11 billion* in federal student aid funds, and sought to recover three times that amount as damages. *Id.* at 438.

Congress's judgment that the severe sanctions of civil penalties and treble damages should be imposed only for "false or fraudulent" claims—not for unspoken "certifications" that would be considered neither false nor fraudulent at common law—is abundantly sensible.

The modern contractual and regulatory environment is far different from and more expansive than that in existence during the Civil War, when the FCA was first enacted. The typical federal program carries with it hundreds or thousands of requirements. It defies reason to hold that a contractor or program participant certifies compliance with every one of them when it bills for goods or services provided. Without an express certification of compliance or actual falsity, the claim is not "false or fraudulent" under the FCA.

II. Any Theory Of Implied Certification Must Rest On Noncompliance With An Expressly Stated Condition Of Payment

If the implied-certification theory is recognized at all, its application must be limited to situations in which a defendant requests payment in violation of an expressly designated precondition to payment. The decision below, however, held that "a material condition of payment" "need not be 'expressly designated'" as such in any statute, regulation, or contract provision. Pet. App. 13 (quoting *Hutcheson*, 647 F.3d at 387-388). That holding represents a mistaken—and dangerous—expansion of the implied-certification theory. The only understanding of implied certification that is conceivably consistent with the theory's underlying logic and the FCA's

scienter standards is one limited to noncompliance with expressly designated preconditions to payment. Moreover, any broader conception of the implied-certification theory would deprive those who do business with the government of fair notice, and allow regulation-through-litigation by *qui tam* relators to supersede the government's calibrated mechanisms for enforcing compliance.

A. The Implied-Certification Theory Applies Only When Compliance Is An Express Condition Precedent To Payment

1. The implied-certification theory rests on the premise that a request for payment should be understood as an implicit representation that the claimant is in full compliance with the statutory, regulatory, and contractual provisions entitling it to payment. If that premise is accepted despite the arguments made in Point I above, it can justify imposition of liability on an implied-certification theory only when the defendant has violated an obligation that is tied to the claim's eligibility for payment in a clear and ascertainable way.

For that reason, most lower courts applying the implied-certification theory have distinguished between requirements that are "conditions of payment" and other requirements that are not, such as those that are merely "conditions of participation" in a government program. See, *e.g.*, *United States ex rel. Ketroser* v. *Mayo Found.*, 729 F.3d 825, 831 (8th Cir. 2013); *Chesbrough* v. *Visiting Physicians Ass'n, P.C.*, 655 F.3d 461, 468 (6th Cir. 2011); *United States ex rel. Conner* v. *Salina Regional Health Center*, 543 F.3d 1211, 1221 (10th Cir. 2008); *United States ex*

rel. Siewick v. *Johnson Science & Eng'g, Inc.*, 214 F.3d 1372, 1376 (D.C. Cir. 2000); *Mikes*, 274 F.3d at 702; see also *Southland*, 326 F.3d at 679-680 (en banc) (Jones, J., joined by Smith, Barksdale, DeMoss & Clement, JJ., specially concurring).

The distinction between conditions of payment and other requirements that are not tied to payment makes eminent sense. The requirement that an implied-certification theory be based on noncompliance with a prerequisite to payment "has to do with more than just the materiality of a false certification; it ultimately has to do with whether it is fair to find a false certification or false claim for payment in the first place." *Steury I*, 625 F.3d at 269. Unless a claimant is on notice that the right to receive payment is conditioned on compliance with a particular requirement, there would be no logical basis to infer that, in submitting a claim for payment, the claimant impliedly represents that it has complied with that requirement. See *ibid*.

Moreover, if the implied-certification theory is not restricted to cases in which compliance is a precondition to payment, it will transform the FCA from a remedy targeting intentional fraud against the government into an all-purpose remedy for virtually every violation of a federal statute, regulation, or contractual requirement. As courts have routinely observed, the FCA "was not designed for use as a blunt instrument" to enforce compliance with those legal standards. *Mikes*, 274 F.3d at 699; see also, *e.g.*, *Steury I*, 625 F.3d at 269; *United States ex rel. Hopper* v. *Anton*, 91 F.3d 1261, 1266 (9th Cir. 1996).

The condition of payment must be expressly designated as such (in advance). If compliance with a

particular statute, regulation, or contract provision is truly a prerequisite to payment of a claim, the direct link between the defendant's implied "false statement" and the government's payment of the claim should be objectively ascertainable from the contract, regulation, or statute. Any other rule fails to provide concrete guidance regarding what legal requirements will be a basis for imposing the FCA's punitive sanctions under the implied-certification theory. The absence of concrete guidance, in turn, subjects program participants and contractors to an unfair risk that any noncompliance with a requirement will later be found to have been "material" to the government's payment decision, whether or not any relationship between the requirement and payment was discernible when the claim was made.

The court of appeals' contrary holding deprives defendants of fair notice of the acts that may lead to the imposition of "essentially punitive," *Vermont Agency*, 529 U.S. at 784, liability for treble damages and civil penalties under the FCA. The Due Process Clause requires fair notice of what conduct may be punished, civilly or criminally. Notice that conduct is forbidden by a statute, contract, or regulation is not the same as notice that it may result in punitive sanctions. The theory of the court of appeals is therefore constitutionally suspect. "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." *BMW of N. Am., Inc.* v. *Gore*, 517 U.S. 559, 574 (1996); see also *Johnson* v. *United States*, 135 S. Ct. 2551, 2556-2557 (2015) (due process principle of fair notice applied to criminal

statute increasing the severity of punishment for concededly unlawful conduct).

The position that a requirement need not be a condition of payment—and identifiable in advance as such—therefore should be rejected under the canon of constitutional avoidance. See *Skilling* v. *United States*, 561 U.S. 358, 412 (2010); *Zadvydas* v. *Davis*, 533 U.S. 678, 689 (2001). In any event, that construction of the FCA does not reflect the intent of Congress.

The theory adopted by the court of appeals lends itself to abuse by watering down both the bedrock requirement that a claim be "false or fraudulent" and the separate requirement (recognized by most courts of appeals) that it be material. Materiality is defined expansively under the FCA to mean "a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property." 31 U.S.C. § 3729(b)(4). Plaintiffs' lawyers will have a field day if such an already-low threshold need not be shown by express language but can instead be met by *post hoc* evidence of, and speculation about, the supposed materiality of a condition.[7]

Examples of such abuses abound. In *United States ex rel. Barrett v. Columbia/HCA Healthcare*

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[7] Cf. 1 Boese, *supra*, § 2.03[G][3][a], at 2-210 ("With the statutory adoption of the more lenient test for materiality under which a false statement only has to 'be capable of influencing' the government's decision to pay the claim, courts began to rely more heavily on the prerequisite to payment standard as a limit on liability under the false implied certification theory.").

Corp., 251 F. Supp. 2d 28 (D.D.C. 2003), the court applied the implied-certification theory and held that compliance with the Medicare anti-kickback statute, 42 U.S.C. § 1320a–7b(b), and the Stark Law, *id.* § 1395nn, was a precondition to reimbursement under the Medicare program. But that determination was based in large part on language that was added to a Medicare form *after* the claims at issue were submitted. The court held that the timing of the language's inclusion did "not negate its evidentiary value in proving that the government would not have paid the claims had it known of the alleged violations." 251 F. Supp. 2d at 32 n.2.

In *SAIC*, the government claimed that a contractor had violated the FCA by requesting payment under two contracts to provide technical services to the Nuclear Regulatory Commission despite having violated contractual provisions governing potential conflicts of interest. See 626 F.3d at 1261-1263. Although the contracts contained provisions setting forth procedures to mitigate a disclosed conflict of interest, see *id.* at 1262, the D.C. Circuit nonetheless upheld the jury's conclusion that the contractor's violation of the conflict-of-interest rules was material to the government's payment decision, see *id.* at 1271. The court did not rely on any express provision in the contract that would have alerted the contractor that the rules were preconditions to payment. Instead, the court invoked after-the-fact witness testimony that the conflict-of-interest obligations "were important to the overall purpose of the contract," with particular emphasis placed on the self-serving testimony of Nuclear Regulatory Commission officials who stated that, "had they been aware of [the contractor's] apparent or actual conflicts * * *

they would not have awarded the two contracts, nor would they have made payments under those contracts." *Id.* at 1271. See also *United States ex rel. Bidani* v. *Lewis*, 264 F. Supp. 2d 612, 615 (N.D. Ill. 2003) (relying on statement of interest filed by United States asserting that specific federal law "is a critical provision of the Medicare statute" and thus that "compliance with it is material to the government's treatment of claims for reimbursement").

Imposing liability for treble damages and civil penalties based on such after-the-fact evidence that the government purportedly conditioned payment on compliance—really just self-serving *assertions* of materiality, in many cases, coupled with a tenuous construction of "false or fraudulent"—is patently unfair and constitutionally suspect. It also demonstrates the incoherence of any approach to the implied-certification theory that treats the submission of a claim for payment as an implied assurance that all conditions that a court might subsequently deem to be material have been satisfied. It is simply implausible to believe that, by submitting a claim, the claimant intends to represent anything more than compliance with expressly designated conditions of payment. *Steury I*, 625 F.3d at 269; *Mikes*, 274 F.3d at 700.

2. That conclusion is reinforced by the FCA's scienter provisions. The FCA provides that liability may be imposed for *knowingly* submitting a false or fraudulent claim, or causing one to be submitted, 31 U.S.C. § 3729(a)(1)(A), and then defines "knowingly" to mean acting with actual knowledge, acting in deliberate ignorance, or acting in reckless disregard

of the truth or falsity of information, *id.* § 3729(b)(1)(A)(i)-(iii).

In an implied-certification case, the FCA's knowledge element requires a plaintiff to establish the defendant knew not only that that it was in violation of an underlying legal requirement, but also that the legal requirement alleged to have been violated was a precondition to receiving payment. Without knowledge of the link between compliance and payment, there is no basis to conclude that the defendant's claim for payment amounted to a certification of compliance with the condition.

Even under the FCA's most expansive state-of-mind theory—reckless disregard—an express connection between compliance and payment is necessary to establish the required scienter. As this Court explained in *Safeco Insurance Co. of America* v. *Burr*, 551 U.S. 47 (2007), in the civil context, recklessness is generally understood to mean "conduct violating an objective standard: action entailing 'an unjustifiably high risk of harm that is either known or so obvious that it should be known.'" *Id.* at 68 (quoting *Farmer* v. *Brennan*, 511 U.S. 825, 836 (1994)); see also *id.* at 69 ("It is this high risk of harm, *objectively assessed*, that is the essence of recklessness at common law." (emphasis added)). *Safeco* involved the question whether the defendant's violation of the Fair Credit Reporting Act (FCRA) had been reckless. See *id.* at 68. In answering that question, the Court held that "a company subject to FCRA does not act in reckless disregard unless the action is not only a violation under a reasonable reading of the statute's terms, but shows that the company ran a risk of violating the law substantially greater than the risk

associated with a reading that was merely careless." *Id.* at 69. In other words, when a defendant's understanding of the statute was not "objectively unreasonable," there is no recklessness. *Ibid.* Because the FCRA was "silent" on the relevant legal question, and the defendant had not been "warned * * * away from the view it took" by authoritative judicial decisions or administrative guidance, the Court concluded that the defendant's reading of the FCRA was not objectively unreasonable. *Id.* at 70.

The question in any implied-certification case mirrors the one addressed by this Court in *Safeco*: Has the defendant contractor acted in reckless disregard of the risk that its claim for payment will be understood as an implied certification that an underlying legal requirement has been satisfied? As in *Safeco*, the answer to that question depends on an analysis of the underlying legal requirements—including statutes, regulations, and contractual language. And, as *Safeco* makes clear, its resolution depends on whether it is "objectively unreasonable," 551 U.S. at 70, to conclude that the legal requirement is not a precondition of payment. See also *United States ex rel. Purcell* v. *MWI Corp.*, 807 F.3d 281, 287-288 (D.C. Cir. 2015) (holding that the FCA does not "reach those claims made based on reasonable but erroneous interpretations of a defendant's legal obligations," and noting that this rule helps to "avoid[] the potential due process problems posed by penalizing a private party for violating a rule without first providing adequate notice of the substance of the rule" (internal quotation marks omitted)).

When a requirement is not expressly designated as a condition of payment, it is not objectively unreasonable to conclude that a request for payment is not implicitly certifying compliance with that requirement. After all, program participants and contractors are subject to voluminous legal obligations, most of which are *not* conditions of payment. See, *e.g.*, *Wilkins*, 659 F.3d at 310. In the absence of an express designation, the natural conclusion is that a requirement is not a condition of payment. That inference is stronger still when certain requirements in a regulatory scheme are expressly designated as conditions of payment while others are not, as is the case here (see pp. 8-9, *supra*), or certain express certifications are required to be made in a claim for payment. *Expressio unius est exclusio alterius*. Accordingly, a condition of payment must be stated expressly in order to support the requisite scienter in an implied-certification case. See *Mikes*, 274 F.3d at 700.

3. The sweeping theory of implied certification applied by the court of appeals below threatens to impose "almost boundless" liability under the FCA, a prospect this Court rejected in *Allison Engine Co.*, 553 U.S. at 669. If the plaintiff's theory of implied certification need not be tethered to the text of the statute, regulation, or contract at issue, then there is little to stop *qui tam* relators from pleading claims based on perceived violations of technical and obscure industry standards, environmental regulations, procurement manuals, and contractual terms. Given the pervasiveness and complexity of regulation governing those who do business with the government, the scope of potential claims is nearly endless.

Moreover, allowing FCA plaintiffs to treat every condition of participation as though it were a condition of payment would permit private *qui tam* relators to usurp the government's primary role in evaluating and adjudicating violations of its regulations. "[I]t is ironical that if we allowed appellants, though they are ostensibly acting on behalf of the Government, to bring suit based on United Health's non-compliance with marketing regulations, we would short-circuit the very remedial process the Government has established to address non-compliance with those regulations. 'It would * * * be curious to read the FCA, a statute intended to protect the government's fiscal interests, to undermine the government's own regulatory procedures.'" *Wilkins*, 659 F.3d at 310 (quoting *Conner*, 543 F.3d at 1222).

In this case, for example, the MassHealth program has numerous remedies available to it to address violations of its regulations, ranging from administrative fines to suspension from the program, see 130 Mass. Code Regs. §§ 450.238-450.249, as well as actions for breach of contract. State licensing authorities and medical regulators may also act to address violations of the rules and standards they enforce. In choosing among those remedies, the responsible public agencies are likely to have due regard for all the considerations that may inform the public interest, including the degree of culpability involved in a regulatory violation and the risk that punitive liability may diminish the resources available to serve program participants. When the same underlying requirements are enforced by *qui tam* relators, however, there is no equivalent basis for confidence.

The facts of this case illustrate the problem: Massachusetts regulators thoroughly investigated the alleged regulatory infractions of which relators complain, and responded with corrective measures that involved no monetary penalty except a $1,000 levy against a single individual. See pp. 11-13, *supra*. Success by relators in this FCA action, by contrast, would result in the stigma of a determination that petitioner "defrauded" the government, treble damages, civil penalties, and liability for relators' attorneys' fees.

In its cases addressing the implication of private rights of action under federal statutes or Section 1983, this Court has been sensitive to the reality that many statutes provide general directions that are appropriate for contractual or administrative enforcement, but are ill suited to enforcement through litigation by private plaintiffs. See, *e.g.*, *Blessing* v. *Freestone*, 520 U.S. 329, 343 (1997) (describing the requirement of "substantial compliance" with Title IV-D of the Social Security Act as a "yardstick" for the Secretary of Health and Human Services to measure performance of a program as a whole, rather than a source of individual rights); *Suter* v. *Artist M.*, 503 U.S. 347, 361-362 (1992) (holding that "reasonable efforts" provision of the Adoption Assistance and Child Welfare Act of 1980 was to be enforced by the Secretary of Health and Human Services, rather than private litigants).[8]

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[8] See also, *e.g.*, *Armstrong* v. *Exceptional Child Center, Inc.*, 135 S. Ct. 1378, 1390 (2015) (Breyer, J., concurring in part and concurring in the judgment) ("like the majority, I would ask why * * * other forms of relief are

The same principle applies in the context of the FCA. See, *e.g.*, *United States ex rel. Hobbs* v. *Medquest Assocs., Inc.*, 711 F.3d 707, 717 (6th Cir. 2013) ("[T]he 'blunt[ness]' of the FCA's hefty fines and penalties makes them an inappropriate tool for ensuring compliance with technical and local program requirements * * *. Such compliance may of course be enforced administratively through suspension, disqualification, or other remedy." (quoting *Mikes,* 274 F.3d at 699)). If *qui tam* relators are permitted to wander from the Act's core anti-fraud purpose, their suits will interfere with administration of federal programs by the responsible public officials.

B. The FCA's Materiality and Scienter Elements Provide No Assurance That Meritless FCA Cases Will Be Dismissed

Even courts that have adopted expansive versions of the implied-certification theory have acknowledged that it "is prone to abuse by the government and *qui tam* relators who, seeking to take advantage of the FCA's generous remedial scheme, may attempt

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inadequate," citing various steps the federal government may take to enforce statutory requirements in the Medicaid context); *Gonzaga University* v. *Doe*, 536 U.S. 273, 289-290 (2002) (Congress's decision to give remedial responsibility and discretion to a federal official counsels against recognition of a cause of action to enforce rights under 42 U.S.C. § 1983); *Alexander* v. *Sandoval*, 532 U.S. 275, 289-291 (2001) (the availability of administrative remedies can in some instances show that Congress did not intend private enforcement of binding substantive requirements).

to turn the violation of minor contractual provisions into an FCA action." *SAIC*, 626 F.3d at 1270; see also *United States* v. *Triple Canopy, Inc.*, 775 F.3d 628, 637 (4th Cir. 2015). They have suggested, however, that "this very real concern can be effectively addressed through strict enforcement of the Act's materiality and scienter requirements." *SAIC*, 626 F.3d at 1270; *Triple Canopy*, 775 F.3d at 637. That optimistic assessment is incorrect. Attention to materiality and scienter does not obviate the need to enforce the FCA's requirement that a claim be "false or fraudulent" in the first place.

At a fundamental level, resort to materiality misses the point: It is unrealistic to understand the submission of a claim for payment as guaranteeing compliance with every condition of a contract or federal program that a court or jury might later deem to be material. See pp. 42-43, 47, *supra*. Moreover, as explained at pp. 45-47 above, if the materiality inquiry is not focused on the text of the relevant legal materials, then it reduces to an inherently unpredictable and fact-intensive judgment, governed by an exceedingly forgiving legal standard. See 31 U.S.C. § 3729(b)(4). Likewise, the application of the FCA's scienter provisions is often a highly fact-intensive question, which means it will seldom be susceptible to resolution on a motion to dismiss or even on summary judgment.

It is not a realistic answer to say that defendants with meritorious defenses will prevail at summary judgment, or at trial. Just as the "[c]ertification of a large class may so increase the defendant's potential damages liability and litigation costs that he may find it economically prudent *to settle and to abandon*

a meritorious defense," *Coopers & Lybrand* v. *Livesay,* 437 U.S. 463, 476 (1978) (emphasis added), so too will the possibility of treble damages, per-claim civil penalties, and the opprobrium of being found to have engaged in "fraud" against the government—as well as the burdens of costly and intrusive discovery—induce a great many defendants to settle even meritless FCA litigation. See, *e.g.*, *Smith* v. *Duffey*, 576 F.3d 336, 340 (7th Cir. 2009) (discovery in "complex litigation can be so steep as to coerce a settlement on terms favorable to the plaintiff even when his claim is very weak"); *International Data Bank, Ltd.* v. *Zepkin*, 812 F.2d 149, 153 (4th Cir. 1987) (treble-damages provisions increase danger of defendants settling nuisance suits); see also, *e.g.*, John T. Boese & Beth C. McClain, *Why* Thompson *Is Wrong: Misuse of the False Claims Act to Enforce the Anti-Kickback Act*, 51 Ala. L. Rev. 1, 18 (1999) (noting that the potential FCA liability "places great pressure on defendants to settle even meritless suits"). Even a remote chance of catastrophic liability is a risk that few rational defendants are willing to accept.

The risk that even meritless FCA suits will create substantial settlement pressure is thus a powerful reason to reject a rule of law that would insulate many claims from a motion to dismiss. See, *e.g.*, *Wal-Mart Stores, Inc.* v. *Samara Bros.*, 529 U.S. 205, 214 (2000) (rejecting proposed legal standard for determining inherent distinctiveness under the Lanham Act in part because "[s]uch a test would rarely provide the basis for summary disposition of an anticompetitive strike suit"); *Blue Chip Stamps* v. *Manor Drug Stores*, 421 U.S. 723, 742 (1975) (holding that private plaintiffs suing under Section 10(b)

of Securities Exchange Act of 1934 must be purchasers or sellers of securities, in part because allowing suit by those who claim they *would have* purchased the security would render nuisance cases "virtually impossible to dispose of prior to trial other than by settlement"); see also *Dura Pharm., Inc.* v. *Broudo*, 544 U.S. 336, 347 (2005); *Reiter* v. *Sonotone Corp.*, 442 U.S. 330, 345 (1979).

Case-by-case enforcement (even "strict" enforcement) of the FCA's materiality and scienter requirements, therefore, is a woefully inadequate substitute for an appropriate construction of what constitutes a "false or fraudulent" claim. The incentives created by the Act's "generous remedial scheme," *SAIC*, 626 F.3d at 1270, are real and are demonstrated by unhappy experience. To prevent FCA litigation from becoming an device to reward "bounty hunters," *United States ex rel. Bogina* v. *Medline Industries*, ___ F.3d ___, 2016 WL 25611, at *2 (7th Cir. 2016)—targeting any and all deep-pocketed participants in complex government programs—this Court should either reject the implied-certification theory entirely or limit it to cases in which the defendant is alleged to have violated an express condition of payment, so identified in advance.

III. The Decision Below Should Be Reversed

If this Court adopts petitioner's position on either of the two questions presented, the judgment of the court of appeals should be reversed.

A. The judgment of the court of appeals cannot be sustained if this Court rejects the implied-certification theory of falsity under the FCA. Although the court of appeals purported to "eschew[] distinctions"

between implied and express certification theories of liability, Pet. App. 12, its judgment plainly rests on the premise that the submission of a claim for payment can be understood as an implied certification of compliance with the claimant's underlying legal duties. See Pet. App. 17-18 n.14 (noting that relators have not alleged that any of petitioner's claims contained any explicit falsehoods, and stating that, each time petitioner submitted a claim, it "*implicitly* communicated that it had conformed to the relevant program requirements" (emphasis added)). That is the essence of the implied-certification theory. If this Court rejects the basic premise of the court of appeals' analysis, then the judgment must be reversed.

B. The judgment below also cannot be sustained if this Court concludes that only an expressly designated condition of payment can serve as a predicate for the implied-certification theory. None of the Massachusetts regulations invoked by the court of appeals expressly conditioned reimbursement for individual claims on compliance.

The court of appeals held that MassHealth reimbursement was conditioned on adequate supervision of staff members at petitioner's Lawrence clinic. The court reasoned that Section 429.439(C) requires a satellite clinic to have a full-time clinical director who "meet[s] all of the requirements in [130 Mass. Code Regs.] § 429.423(B)," and that regulation in turn includes "overall supervision of staff performance," 130 Mass. Code Regs. § 429.423(B)(2)(c), among the list of the clinical director's "specific responsibilities." But nothing in the regulations expressly states that the "responsibilities" included in

the second subparagraph of Section 429.423(B) correspond to the "requirements" mentioned in Section 429.439(C). Instead, the far more natural conclusion is that Section 429.439(C) refers to the qualifications set forth in the first subparagraph of Section 429.423(B)—including licensure, required experience in the field, and educational requirements. Unlike those objectively verifiable qualifications, the "responsibilities" listed in Section 429.423(B) have no clear yardstick for satisfaction. See, *e.g.*, 130 Mass. Code Regs. § 429.423(B)(2)(d) ("accountability for adequacy and appropriateness of patient care"); *id.* § 429.423(B)(2)(g) ("program evaluation"); *id.* § 429.423(B)(2)(i) ("development of in-service training for professional staff"). It is therefore implausible that those highly general aspects of the clinical director's job description constitute "requirements" on which payment is conditioned in Section 429.439(C).

In upholding relators' allegations that petitioner had submitted false claims by seeking reimbursement while the Lawrence clinic was in violation of staffing requirements, the court of appeals relied on the same mistaken premise that the "responsibilities" set forth in Section 429.423(B)(2) are "requirements" within the meaning of Section 429.439. That leap is what allowed the court of appeals to conclude that reimbursement was conditioned on whether the Lawrence clinic's clinical director "employ[ed] adequate psychiatric staff." 130 Mass. Code Regs. § 429.423(B)(2)(e). But, as just explained, there is no express connection between the "requirements" mentioned in Section 429.439(C) and clinical director job "responsibilities." Thus, reimbursement was not ex-

pressly premised on employment of "adequate psychiatric staff."

Moreover, even if (contrary to fact) employment of "adequate" psychiatric staff had been an express condition of payment, there was no express link between that regulatory requirement and the Massachusetts DPH regulations that the court of appeals invoked in concluding that relators had plausibly pleaded a lack of adequate psychiatric personnel. See Pet. App. 21. Those regulations do not state that they are preconditions to payment under the MassHealth program (which is administered by a separate state agency), and there is no sound basis for the court of appeals' apparent conclusion that Section 429.423(B)(2)(e) incorporates them by reference.

The court of appeals nonetheless stated that "the provisions at issue in this case clearly impose conditions of payment." Pet. App. 15. It is unclear exactly what the court of appeals intended to convey by characterizing the regulations that way, but it evidently was not that they were expressly designated as conditions of payment. After all, the court emphasized that "[p]reconditions of payment * * * need not be 'expressly designated.'" Pet. App. 13 (quoting *Hutcheson*, 647 F.3d at 387-388). The court of appeals' decision is thus irreconcilable with the requirement that preconditions to payment be expressly designated in order to support an implied-certification theory, and the judgment should accordingly be reversed if this Court adopts petitioner's position on the second question presented.

CONCLUSION

The judgment of the court of appeals should be reversed.

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
McDermott Will & Emery LLP
500 N. Capitol Street, NW
Washington, DC 20001
(202) 756-8000

ROY T. ENGLERT, JR.
Counsel of Record
GARY A. ORSECK
MARK T. STANCIL
MICHAEL L. WALDMAN
DONALD BURKE
Robbins, Russell, Englert, Orseck, Untereiner & Sauber LLP
1801 K Street, NW
Washington, DC 20006
(202) 775-4500
renglert@robbinsrussell.com

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APPENDIX—STATUTORY AND REGULATORY PROVISONS

1. 31 U.S.C. § 3729 provides:

False Claims

(a) Liability for certain acts.—

(1) In general.—Subject to paragraph (2), any person who—

(A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;

(B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim;

(C) conspires to commit a violation of subparagraph (A), (B), (D), (E), (F), or (G);

(D) has possession, custody, or control of property or money used, or to be used, by the Government and knowingly delivers, or causes to be delivered, less than all of that money or property;

(E) is authorized to make or deliver a document certifying receipt of property used, or to be used, by the Government and, intending to defraud the Government, makes or delivers the receipt without completely knowing that the information on the receipt is true;

(F) knowingly buys, or receives as a pledge of an obligation or debt, public property from an officer or employee of the Government, or a member of the Armed Forces, who lawfully may not sell or pledge property; or

(G) knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government,

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 (28 U.S.C. 2461 note; Public Law 104-4101), plus 3 times the amount of damages which the Government sustains because of the act of that person.

(2) Reduced damages.—If the court finds that—

(A) the person committing the violation of this subsection furnished officials of the United States responsible for investigating false claims violations with all information known to such person about the violation within 30 days after the date on which the defendant first obtained the information;

(B) such person fully cooperated with any Government investigation of such violation; and

(C) at the time such person furnished the United States with the information about the violation, no criminal prosecution, civil action, or administrative action had commenced under this title with respect to such violation, and the person did not have actual knowledge of the existence of an investigation into such violation,

the court may assess not less than 2 times the amount of damages which the Government sustains because of the act of that person.

(3) Costs of civil actions.—A person violating this subsection shall also be liable to the United States Government for the costs of a civil action brought to recover any such penalty or damages.

(b) Definitions.—For purposes of this section—

(1) the terms "knowing" and "knowingly" —

(A) mean that a person, with respect to information—

(i) has actual 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; and

(B) require no proof of specific intent to defraud;

(2) the term "claim"—

(A) means any request or demand, whether under a contract or otherwise, for money or property and whether or not the United States has title to the money or property, that—

(i) is presented to an officer, employee, or agent of the United States; or

(ii) is made to a contractor, grantee, or other recipient, if the money or property is to be spent or used on the Government's behalf or to advance a Government program or interest, and if the United States Government—

(I) provides or has provided any portion of the money or property requested or demanded; or

(II) will reimburse such contractor, grantee, or other recipient for any portion of the money or property which is requested or demanded; and

(B) does not include requests or demands for money or property that the Government has paid to an individual as compensation for Federal employment or as an income subsidy with no restrictions on that individual's use of the money or property;

(3) the term "obligation" means an established duty, whether or not fixed, arising from an express or implied contractual, grantor-grantee, or licensor-licensee relationship, from a fee-based or similar relationship, from statute or regulation, or from the retention of any overpayment; and

(4) the term "material" means having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property.

(c) Exemption from disclosure.—Any information furnished pursuant to subsection (a)(2) shall be exempt from disclosure under section 552 of title 5.

(d) Exclusion.—This section does not apply to claims, records, or statements made under the Internal Revenue Code of 1986.

2. 31 U.S.C. § 3730 provides in pertinent part:

Civil Actions for False Claims

(a) Responsibilities of the Attorney General.—The Attorney General diligently shall investigate a violation under section 3729. If the Attorney General finds that a person has violated or is violating section 3729, the Attorney General may bring a civil action under this section against the person.

(b) Actions by private persons.—(1) A person may bring a civil action for a violation of section 3729 for the person and for the United States Government. The action shall be brought in the name of the Government. The action may be dismissed only if the court and the Attorney General give written consent to the dismissal and their reasons for consenting.

(2) A copy of the complaint and written disclosure of substantially all material evidence and information the person possesses shall be served on the Government pursuant to Rule 4(d)(4) of the Federal Rules of Civil Procedure. The complaint shall be filed in camera, shall remain under seal for at least 60 days, and shall not be served on the defendant until the court so orders. The Government may elect to intervene and proceed with the action within 60 days after it receives both the complaint and the material evidence and information.

(3) The Government may, for good cause shown, move the court for extensions of the time during which the complaint remains under seal under paragraph (2). Any such motions may be supported by affidavits or other submissions in camera. The defendant shall not be required to respond to any complaint filed under this section until 20 days after

the complaint is unsealed and served upon the defendant pursuant to Rule 4 of the Federal Rules of Civil Procedure.

(4) Before the expiration of the 60-day period or any extensions obtained under paragraph (3), the Government shall—

(A) proceed with the action, in which case the action shall be conducted by the Government; or

(B) notify the court that it declines to take over the action, in which case the person bringing the action shall have the right to conduct the action.

(5) When a person brings an action under this subsection, no person other than the Government may intervene or bring a related action based on the facts underlying the pending action.

(c) Rights of the parties to qui tam actions.—(1) If the Government proceeds with the action, it shall have the primary responsibility for prosecuting the action, and shall not be bound by an act of the person bringing the action. Such person shall have the right to continue as a party to the action, subject to the limitations set forth in paragraph (2).

(2)(A) The Government may dismiss the action notwithstanding the objections of the person initiating the action if the person has been notified by the Government of the filing of the motion and the court has provided the person with an opportunity for a hearing on the motion.

(B) The Government may settle the action with the defendant notwithstanding the objections of the person initiating the action if the court determines, after a hearing, that the proposed settlement is fair,

adequate, and reasonable under all the circumstances. Upon a showing of good cause, such hearing may be held in camera.

(C) Upon a showing by the Government that unrestricted participation during the course of the litigation by the person initiating the action would interfere with or unduly delay the Government's prosecution of the case, or would be repetitious, irrelevant, or for purposes of harassment, the court may, in its discretion, impose limitations on the person's participation, such as—

(i) limiting the number of witnesses the person may call;

(ii) limiting the length of the testimony of such witnesses;

(iii) limiting the person's cross-examination of witnesses; or

(iv) otherwise limiting the participation by the person in the litigation.

(D) Upon a showing by the defendant that unrestricted participation during the course of the litigation by the person initiating the action would be for purposes of harassment or would cause the defendant undue burden or unnecessary expense, the court may limit the participation by the person in the litigation.

(3) If the Government elects not to proceed with the action, the person who initiated the action shall have the right to conduct the action. If the Government so requests, it shall be served with copies of all pleadings filed in the action and shall be supplied with copies of all deposition transcripts (at

the Government's expense). When a person proceeds with the action, the court, without limiting the status and rights of the person initiating the action, may nevertheless permit the Government to intervene at a later date upon a showing of good cause.

(4) Whether or not the Government proceeds with the action, upon a showing by the Government that certain actions of discovery by the person initiating the action would interfere with the Government's investigation or prosecution of a criminal or civil matter arising out of the same facts, the court may stay such discovery for a period of not more than 60 days. Such a showing shall be conducted in camera. The court may extend the 60-day period upon a further showing in camera that the Government has pursued the criminal or civil investigation or proceedings with reasonable diligence and any proposed discovery in the civil action will interfere with the ongoing criminal or civil investigation or proceedings.

(5) Notwithstanding subsection (b), the Government may elect to pursue its claim through any alternate remedy available to the Government, including any administrative proceeding to determine a civil money penalty. If any such alternate remedy is pursued in another proceeding, the person initiating the action shall have the same rights in such proceeding as such person would have had if the action had continued under this section. Any finding of fact or conclusion of law made in such other proceeding that has become final shall be conclusive on all parties to an action under this section. For purposes of the preceding sentence, a

finding or conclusion is final if it has been finally determined on appeal to the appropriate court of the United States, if all time for filing such an appeal with respect to the finding or conclusion has expired, or if the finding or conclusion is not subject to judicial review.

(d) Award to qui tam plaintiff.—(1) If the Government proceeds with an action brought by a person under subsection (b), such person shall, subject to the second sentence of this paragraph, receive at least 15 percent but not more than 25 percent of the proceeds of the action or settlement of the claim, depending upon the extent to which the person substantially contributed to the prosecution of the action. Where the action is one which the court finds to be based primarily on disclosures of specific information (other than information provided by the person bringing the action) relating to allegations or transactions in a criminal, civil, or administrative hearing, in a congressional, administrative, or Government2 Accounting Office report, hearing, audit, or investigation, or from the news media, the court may award such sums as it considers appropriate, but in no case more than 10 percent of the proceeds, taking into account the significance of the information and the role of the person bringing the action in advancing the case to litigation. Any payment to a person under the first or second sentence of this paragraph shall be made from the proceeds. Any such person shall also receive an amount for reasonable expenses which the court finds to have been necessarily incurred, plus reasonable attorneys' fees and costs. All such expenses, fees, and costs shall be awarded against the defendant.

(2) If the Government does not proceed with an action under this section, the person bringing the action or settling the claim shall receive an amount which the court decides is reasonable for collecting the civil penalty and damages. The amount shall be not less than 25 percent and not more than 30 percent of the proceeds of the action or settlement and shall be paid out of such proceeds. Such person shall also receive an amount for reasonable expenses which the court finds to have been necessarily incurred, plus reasonable attorneys' fees and costs. All such expenses, fees, and costs shall be awarded against the defendant.

(3) Whether or not the Government proceeds with the action, if the court finds that the action was brought by a person who planned and initiated the violation of section 3729 upon which the action was brought, then the court may, to the extent the court considers appropriate, reduce the share of the proceeds of the action which the person would otherwise receive under paragraph (1) or (2) of this subsection, taking into account the role of that person in advancing the case to litigation and any relevant circumstances pertaining to the violation. If the person bringing the action is convicted of criminal conduct arising from his or her role in the violation of section 3729, that person shall be dismissed from the civil action and shall not receive any share of the proceeds of the action. Such dismissal shall not prejudice the right of the United States to continue the action, represented by the Department of Justice.

(4) If the Government does not proceed with the action and the person bringing the action conducts

the action, the court may award to the defendant its reasonable attorneys' fees and expenses if the defendant prevails in the action and the court finds that the claim of the person bringing the action was clearly frivolous, clearly vexatious, or brought primarily for purposes of harassment.

* * * * *

(g) Fees and expenses to prevailing defendant.—In civil actions brought under this section by the United States, the provisions of section 2412(d) of title 28 shall apply.

* * * * *

3. 105 Mass. Code Regs. § 140.330 provides:

Satellite Clinics

A satellite clinic must meet, independently of its parent clinic, all the requirements imposed on clinics by 105 CMR 140.000 except that a satellite clinic, as part of the legal entity operating its parent clinic, shall have no separate articles of organization, or bylaws or other charter of its own, and no separate governing body, shareholders, members, or officers.

4. 105 Mass. Code Regs. § 140.530 provides:

Staffing

(A) A clinic providing mental health services must provide an adequate number of qualified personnel to fulfill the program's objectives.

(B) Multi-disciplinary Staff.

(1) A multi-disciplinary staff must be available as appropriate for the clients' needs.

(2) A multi-disciplinary staff must be comprised of mental health professionals who meet the requirements set forth under 105 CMR 140.530(C). The staff may also include other related mental health professionals necessary for the provision of intake, evaluation, diagnostic and treatment services.

(C) Personnel Qualifications.

(1) Except as otherwise provided in 105 CMR 140.530(C)(2), the multidisciplinary staff must include:

(a) a psychiatrist who is a physician, as defined in 105 CMR 140.020, and who is board certified by the American Board of Psychiatry and Neurology, or eligible for such certification; and

(b) at least two of the following mental health professionals:

1. Psychologist. A clinical or counseling psychologist licensed by the Massachusetts Board of Registration of Psychologists pursuant to M.G.L. c. 112, §§ 118 through 127 and 251 CMR 3.00.

2. Psychiatric Social Worker. A social worker, as defined in 105 CMR 140.020 who has at least one year's post graduate experience in a mental health setting.

3. Psychiatric Nurse. A registered nurse with a master's degree in psychiatric nursing licensed by the Board of Registration in

Nursing pursuant to M.G.L. c. 112, § 80B and 244 CMR 3.00.

4. Psychiatric Nurse Mental Health Clinical Specialist. A psychiatric nurse mental health clinical specialist licensed by the Board of Registration in Nursing pursuant to M.G.L. c. 112, § 80B and 244 CMR 4.13.

5. Licensed Mental Health Counselor. A licensed mental health counselor licensed by the Board of Registration of Allied Mental Health and Human Service Professions pursuant to M.G.L. c. 112, § 165 and 262 CMR 2.00.

6. Licensed Alcohol and Drug Counselor. An alcohol and drug counselor licensed by the Department pursuant to 105 CMR 168.000.

7. Other Licensed Mental Health and Substance Abuse Practitioners. Other mental health and substance practitioners licensed by the Division of Professional Licensure, the Department or any Board of Registration and deemed by the Department to be mental health and substance abuse professionals.

(2) A clinic whose mental health service consists solely of a psychiatric day treatment program as defined in 105 CMR 140.020, may substitute a rehabilitation counselor or occupational therapist as defined in 105 CMR 140.530(C)(2)(a) and (b) for one of the professionals listed in 105 CMR 140.530(C)(1)(b):

(a) Rehabilitation Counselor. An individual who has at least a master's degree in

rehabilitation or vocational counseling and one year's full-time supervised experience in a mental health setting, or its equivalent.

(b) Occupational Therapist. An individual licensed by the Massachusetts Board of Registration of Allied Health Professions and currently certified or eligible for certification by the American Occupational Therapy Association. The occupational therapist must have at least one year of experience in a mental health setting.

(D) Responsibilities of Clinic Physicians and Psychiatrists.

(1) The clinic shall designate a psychiatrist or other physician to be responsible for the establishment of medical policies and supervision of all medical services.

(2) The following duties shall be performed by clinic psychiatrist(s) or physician(s):

(a) prescribing and monitoring or supervising the prescription of all medications, and

(b) evaluating non-psychiatric, physical health problems and making referrals, when appropriate.

(3) Clinic psychiatrist(s) shall:

(a) participate in case reviews as appropriate,

(b) provide case consultation as necessary, and

(c) participate in the clinic's quality assurance program for the mental health service.

(E) Supervision. All staff members other than those meeting the qualifications set forth in 105 CMR 140.530(C) must be clinically supervised on a regular basis by professional staff members as defined in 105 CMR 140.530(C). The documentation of supervision must be available for review

5. 130 Mass. Code Regs. § 429.401 provides:

Introduction

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 130 CMR 429.000 and 450.000: *Administrative and Billing Regulations.*

6. 130 Mass. Code Regs. § 429.402 provides in pertinent part:

Definitions

The following terms used in 130 CMR 429.000 have the meanings given in 130 CMR 429.402 unless the context clearly requires a different meaning.

* * * * *

Autonomous Satellite Program - 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.

* * * * *

Core Discipline - one of the following disciplines: psychiatry, social work, psychology, or psychiatric nursing (including a psychiatric clinical nurse specialist), most or all of which are represented by the professionals qualified in these disciplines who comprise a mental health center's core team.

* * * * *

Dependent Satellite Program - a mental health center program in a satellite facility that is under the direct clinical management of the parent center.

* * * * *

Mental Health Center (Center) - 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.

* * * * *

Satellite Facility - 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 and that meets the following criteria.

(1) It is open to patients more than 20 hours a week.

(2) It offers more than 40 person hours a week of services to patients.

* * * * *

7. 130 Mass. Code Regs. § 429.422 provides:

Staff Composition Requirements

(A) The mental health center must have a balanced interdisciplinary staffing plan that includes three or more core professional staff members who meet the qualifications outlined in 130 CMR 429.424 for their respective professions. Of these, one must be a psychiatrist, and two must be from separate nonphysician core disciplines, including psychology, social work, or psychiatric nursing. Certain additional staffing requirements are contained in 130 CMR 429.423.

(B) The staff must have specific training and experience to treat the target populations of the center. For example, staff treating children are required to have specialized training and experience in children's services. As further described in 130 CMR 429.424, staff who provide individual, group, family therapy, and multiple family group therapy to members younger than 21 years old must be certified every two years to administer the Child and Adolescent Needs and Strengths (CANS), according to the process established by the Executive Office of Health and Human Services (EOHHS).

(C) For clinic-licensed mental health centers, the staff composition requirements are contained in 130 CMR 429.422 and 429.423. Clinic-licensed mental health centers must employ the equivalent of at least three full-time professional staff members, two of whom must be core team members who meet qualifications outlined in 130 CMR 429.423 for their

respective disciplines. When a clinic-licensed mental health center has ten employees or fewer, the core team must work a minimum of 20 hours a week.

(D) Dependent satellite programs must employ at least two full-time equivalent professional staff members from separate nonphysician core disciplines. The Director of Clinical Services at the parent center must ensure that supervision requirements of 130 CMR 429.438(E) are performed. If the satellite program's staff do not meet the qualifications for core disciplines as outlined in 130 CMR 429.424, they must receive supervision from qualified core staff professionals of the same discipline at the parent center.

(E) For clinic-licensed community health centers, the center must employ at least two half-time professional staff members from separate, nonphysician core disciplines who meet the qualifications outlined in 130 CMR 429.424 for their respective disciplines.

(F) Autonomous satellite programs, as defined in 130 CMR 429.402, must meet the requirement's specified in 130 CMR 429.422(C).

8. 130 Mass. Code Regs. § 429.423 provides:

(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) through (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

130 CMR 429.000 are carried out to meet professionally recognized standards of health care, as required by 130 CMR 450.000: Administrative and Billing Regulations.

(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 psycho-pharmacological 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.

9. 130 Mass. Code Regs. § 429.424 (2011) provides:

Qualifications of Staff by Core Discipline

(A) Psychiatrist.

(1) At least one staff psychiatrist must either currently be certified by the American Board of

Psychiatry and Neurology, or be eligible and applying for such certification.

(2) Any additional psychiatrists must be, at the minimum, licensed physicians in their second year of a psychiatric residency program accredited by the Council on Medical Education of the American Medical Association. Such physicians must be under the direct supervision of a fully qualified psychiatrist.

(3) Any psychiatrist or psychiatric resident who provides individual, group, or family therapy to members under the age of 21 must be certified every two years to administer the CANS, according to the process established by the Executive Office of Health and Human Services (EOHHS).

(B) Psychologist.

(1) At least one staff psychologist must be licensed by the Massachusetts Board of Registration of Psychologists with a specialization listed in clinical or counseling psychology or a closely related specialty.

(2) Additional staff members trained in the field of clinical or counseling psychology or a closely related specialty must

(a) have a minimum of a master's degree or the equivalent graduate study in clinical or counseling psychology or a closely related specialty from an accredited educational institution;

(b) be currently enrolled in or have completed a doctoral program in clinical or counseling psychology or a closely related specialty; and

(c) have had two years of full-time supervised clinical experience subsequent to obtaining a master's degree in a multidisciplinary mental-health setting. (One year of supervised clinical work in an organized graduate internship program may be substituted for each year of experience.) All services provided by such additional staff members must be under the direct and continuing supervision of a psychologist meeting the requirements set forth in 130 CMR 429.424(B)(1).

(3) Any psychologist who provides individual, group, or family therapy to members under the age of 21 must be certified every two years to administer the CANS, according to the process established by the Executive Office of Health and Human Services (EOHHS).

(C) Social Worker.

(1) At least one staff social worker must have received a master's degree in social work from an accredited educational institution and must have had at least two years of full-time supervised clinical experience subsequent to obtaining a master's degree. This social worker must also be licensed or have applied for and have a license pending as an independent clinical social worker by the Massachusetts Board of Registration of Social Workers.

(2) Any additional social workers on the staff must provide services under the direct and

continuous supervision of an independent clinical social worker. Such additional social workers must be licensed or applying for licensure as certified social workers by the Massachusetts Board of Registration of Social Workers and have received a master's degree in social work and completed two years of full-time supervised clinical work in an organized graduate internship program.

(3) Any social worker who provides individual, group, or family therapy to members under the age of 21 must be certified every two years to administer the CANS, according to the process established by the Executive Office of Health and Human Services (EOHHS).

(D) Psychiatric Nurse.

(1) At least one psychiatric nurse must be currently registered by the Massachusetts Board of Registration in Nursing and must have a master's degree in nursing from an accredited National League of Nursing graduate school with two years of full-time supervised clinical experience in a multidisciplinary mental-health setting and be eligible for certification as a clinical specialist in psychiatric/mental-health nursing by the American Nursing Association.

(2) Any other nurses must be currently registered by the Massachusetts Board of Registration in Nursing and must have a bachelor's degree from an educational institution accredited by the National League of Nursing and two years of full-time supervised skilled experience in a multidisciplinary mental-health setting

subsequent to that degree, or a master's degree in psychiatric nursing.

(3) Any psychiatric nurse mental-health clinical specialist who provides individual, group, or family therapy to members under the age of 21 must be certified every two years to administer the CANS, according to the process established by the Executive Office of Health and Human Services (EOHHS).

(E) Counselor.

(1) All counselors and unlicensed staff included in the center 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 CMR 429.424(A) through (D).

(2) All counselors must hold a master's degree in counseling education, counseling psychology, or rehabilitation counseling from an accredited educational institution and must have had two years of full-time supervised clinical experience in a multidisciplinary mental-health setting subsequent to obtaining the master's degree. (One year of supervised clinical work in an organized graduate internship program may be substituted for each year of full-time experience.)

(3) Any counselor who provides individual, group, or family therapy to members under the age of 21 must be certified every two years to administer the CANS, according to the process established by the Executive Office of Health and Human Services (EOHHS).

(F) Occupational Therapist.

(1) Any occupational therapist must be currently registered by the American Occupational Therapy Association and must have

(a) a master's degree in occupational therapy from an accredited program in occupational therapy; or

(b) a bachelor's degree in occupational therapy from an accredited program in occupational therapy and a master's degree in a related field such as psychology, social work, or counseling.

(2) In addition, any occupational therapist must have at least two years of full-time supervised clinical experience subsequent to obtaining a master's degree. (One year of supervised clinical work in an organized graduate internship program may be substituted for each year of full-time experience.)

10. 130 Mass. Code Regs. § 429.438 provides:

Administration

The mental health center must be organized to facilitate effective decision-making by appropriate personnel on administrative, programmatic, and clinical issues.

(A) Organization. The center must establish an organization table showing major operating programs of the facility, with staff divisions, administrative personnel in charge of each program, and their lines of authority, responsibility, and communication.

(B) Fiscal Management. The center must establish a system of business management to ensure accurate accounting for sources and uses of funds and proper expenditure of funds within established budgetary constraints and grant restrictions.

(C) Data Management. The center must develop and maintain a statistical information system to collect client, service utilization, and fiscal data necessary for the effective operation of the center.

(D) Personnel Management. The center must establish and maintain personnel policies and personnel records for each employee.

(E) Supervision.

(1) Each staff member must receive supervision appropriate to the person's skills and level of professional development Supervision must occur within the context of a formalized relationship providing for frequent and regularly scheduled personal contact with the supervisor. Frequency and extent of supervision must conform to the licensing standards of each discipline's Board of Registration, as cited in 130 CMR 429.424.

(2) The center must establish and implement procedures for staff training and evaluation. These procedures must require all staff who must be certified to administer the CANS, as described in 130 CMR 429.424, to complete the certification process established by the Executive Office of Health and Human Services (EOHHS).

11. 130 Mass. Code Regs. § 429.439 provides:

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 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).

12. 130 Mass. Code Regs. § 429.441 provides in pertinent part:

Service Limitations

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(F) Psychological Testing. The MassHealth agency pays a center for psychological testing only when the following conditions are met.

(1) A psychologist who meets the qualifications listed in 130 CMR 429.424(B) either personally administers the testing or personally supervises such testing during its administration by an unlicensed psychologist.

(2) A battery of tests is performed. These tests must meet the following standards:

(a) the tests are published, valid, and in general use, as evidenced by their review in the current edition of the Mental Measurement Yearbook or by their conformity to the Standards for Educational and Psychological Tests of the American Psychological Association;

(b) unless clinically contraindicated due to hearing, physical, or visual impairment or linguistic challenges, a personality evaluation contains the findings of at least two of the following test types or their age-appropriate equivalents: Rorschach, TAT (Thematic Apperception Test), TED (Tasks of Emotional Development), or MMPI (Minnesota Multiphasic Personality Inventory), and one or more of the following test types: figure drawing, Bender Gestalt, or word association;

(c) unless clinically contraindicated due to hearing, physical, or visual impairment or linguistic challenges, intelligence testing includes either a full Wechsler or Stanford-Binet instrument; and

(d) unless clinically contraindicated due to hearing, physical, or visual impairment or linguistic challenges, assessment of brain damage must contain at least the findings of a Wechsler Intelligence Scale and tests of recent memory, visual-space perception, and other functions commonly associated with brain damage.

(3) The MassHealth agency does not pay for

(a) self-rating forms and other paper-and-pencil instruments, unless administered as part of a comprehensive battery of tests;

(b) group forms of intelligence tests; or

(c) a repetition of any psychological test or tests provided by the mental health center or any independent psychologist to the same member within the preceding six months, unless accompanied by documentation demonstrating that the purpose of the repeated testing is to ascertain the following types of changes (submission of such documentation with the claim for payment is sufficient when the psychological test or tests are to be performed on the same member a second time within a six-month period):

1. following such special forms of treatment or intervention as electroshock therapy or psychiatric hospitalization (periodic testing

to measure the member's response to psychotherapy is not reimbursable); or

2. relating to suicidal, homicidal, toxic, traumatic, or neurological conditions.

* * * * *