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 AARP AS AMICUS CURIAE IN SUPPORT OF RESPONDENTS

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INTEREST OF AMICUS CURIAE[1]

AARP is a nonpartisan, nonprofit membership organization dedicated to addressing the needs and interests of people age fifty and older. AARP advocates for access to affordable healthcare and for controlling costs without compromising quality. The False Claims Act's implied certification theory is particularly important to older adults because it is a critical tool for the government, whistleblowers and consumer advocates to address substandard and even life-threatening conditions in Medicaid and Medicare-funded long-term care settings, including nursing facilities.

Through its charitable affiliate, AARP Foundation, AARP has filed amicus curiae briefs in courts throughout the country in support of whistleblowers and others who revealed false claims filed by healthcare providers, especially when the providers exposed vulnerable people to harm as a consequence of their fraudulent activity.

SUMMARY OF ARGUMENT

This Court should uphold the First Circuit Court of Appeals' decision reversing the trial court's dismissal of the Respondents' False Claims Act (FCA) suit against Petitioner. *United States ex rel. Escobar*

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[1] No counsel for a party authored this brief in whole or in part or made a monetary contribution to fund the preparation or submission of this brief. No persons other than amicus, its members or its counsel made such a monetary contribution. The parties consent to the filing of this brief.

v. Universal Health Servs., Inc., 780 F.3d 504 (1st Cir. 2015). Respondents' FCA complaint alleges that Petitioner's mental health clinic (Arbour Counseling Services) submitted false claims for services in connection with the treatment of Respondents' deceased daughter, Yarushka Rivera, and other MassHealth beneficiaries. *Id.* at 510-11. The First Circuit's decision permitting Respondent's suit to proceed was based primarily upon its finding that the Respondents adequately pled their claims alleging that the staff at Arbour was not properly supervised in accordance with Massachusetts law, resulting in the knowing submission of false claims. *Id.* at 514. A Massachusetts Department of Public Health investigation corroborated Respondents' allegations by finding that Petitioner employed 23 unlicensed staff to provide mental health services to low-income MassHealth recipients without supervision for up to 16 years. *Id.* at 510.

As this Court now considers both the viability of the implied certification theory and whether conditions of payment must be explicit or may be implied, Amicus submits this brief to describe the life-saving impact that the implied certification theory has had on ensuring quality of care for all people, but especially people in nursing facilities. Whistleblowers like Respondents play a key role in the remarkable success of the FCA. However, the success of the FCA is not limited to financial recoveries as the government and whistleblowers also use the law to identify and remedy substandard healthcare, while imposing continuing compliance obligations on violators to prevent recidivism.

Because regulators alone cannot address the serious and widespread impact of noncompliance, FCA whistleblowers are needed to identify dangerous conditions that would never otherwise come to light and to prosecute false claims on behalf of the government. The litigation brought by whistleblowers and the government and the global settlements that result from such cases often depend upon the implied certification theory. Many of these settlements would be impossible to achieve if the Court finds that the implied certification theory is either not viable or determines that the theory can only be predicated on explicitly designated conditions of payment.

ARGUMENT

I. THE IMPLIED CERTIFICATION THEORY IS ROOTED IN THE FALSE CLAIMS ACT'S PLAIN LANGUAGE AND STRUCTURE.

Courts interpret the civil FCA broadly, consistent with its remedial purposes. The FCA imposes civil liability on any person who "knowingly presents, or causes to be presented" to the United States or its representatives "a false or fraudulent claim for payment or approval," 31 U.S.C. § 3729(a)(1)(A), or "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim," *Id.* § 3729(a)(1)(B). The FCA defines the term "material" to mean "having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property." *Id.* § 3729 (b)(4).

Unlike Section 3729(a)(1)(B), which imposes liability where a person makes or uses "a false record or statement material to a false or fraudulent claim," Section 3729(a)(1)(A) does not require a false statement of any sort, much less an express false statement on the face of a claim for payment. The contrast between these two provisions of the FCA illustrates that a claim may be impliedly false under Section 3729(a)(1)(A) even when it contains no express false statements. Thus, the "implied certification" theory of liability is anchored in the plain language and structure of the FCA.

A. Both the Express and Implied Certification Theories Are Vital Tools to Address Fraud and Protect People from Substandard Care.

The FCA is the single most effective tool in the fight against fraud perpetrated against the government. From January 2009 to September 2015, the United States Department of Justice recovered more than $26.4 billion in actions under the statute. *See* Press Release, Office of Pub. Affairs, U.S. Dep't of Justice, *Justice Department Recovers $3.5 Billion in False Claims Cases in Fiscal Year 2015* (Dec. 3, 2015), https://www.justice.gov/opa/pr/justice-department-recovers-over-35-billion-false-claims-act-cases-fiscal-year-2015. Whistleblowers like Respondents play a key role in this success. In 2015, more than 85 percent of FCA referrals, investigations and actions were brought by relators pursuant to the *qui tam*

provisions of the statute.[2] *See* Civil Div., U.S. Dep't of Justice, *Fraud Statistics Overview* 2 (Nov. 23, 2015), https://www.justice.gov.opa/file/796866/down load. Whether the government declines or seeks to intervene in a case brought by a *qui tam* relator, "the United States is the real party in interest in any False Claims Act suit." *United States ex rel. Milam v. Univ. of Texas*, 961 F.2d 46, 50 (4th Cir.1992).

The value and success of the FCA is not limited to the government's financial recovery. FCA cases redress fraud by identifying and remedying substandard healthcare, while imposing continuing compliance obligations on violators to prevent recidivism. The information made available in healthcare cases is a critical component of monitoring the quality of care. The government recognizes the positive impact that the FCA has on the quality of healthcare. The Office of Inspector General (OIG) of the Department of Health and Human Services highlighted the positive impact that the FCA has on the quality of care provided to beneficiaries of federal health care programs:

> The OIG, together with our law enforcement partners, has with increasing frequency used the False Claims Act, the Federal Government's

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[2] This percentage was calculated by using the following figures for 2015: the number of non-*qui tam* matters brought by the government (105) added to the number of *qui tam* matters brought by relators (632) comes to 737 FCA matters; therefore, *qui tam* matters represent 85.7% of the total FCA matters for 2015.

> primary civil enforcement tool for fraud, to address poor quality of care. These cases often involve allegations of widespread failures that result in patient harm. In cases involving nursing facilities, systemic problems we have identified that have resulted in substandard care include staffing shortages; improper use of restraints; failure to implement medical orders or services identified on the care plan; failure to provide proper nutrition; failure to ensure that residents are protected from falls, physical abuse, and medication errors; and failure to prevent facility-acquired conditions such as infections and pressure ulcers.

Office of Inspector Gen., U.S. Dep't of Health and Human Servs., *FY 2008 Top Management and Performance Challenges Identified by the Office of Inspector General* 20, http://oig.hhs.gov/publications/challenges/files/TM_Challenges08.pdf.

B. The FCA Does Not Require Explicit Designation of Each Condition of Payment to Plead a Viable Claim.

Petitioner argues that regulatory noncompliance should not give rise to FCA liability, because MassHealth regulations are conditions of participation rather than conditions for receiving reimbursement for services. Pet'r's Br. 58. Essentially, if the Court adopts Petitioner's

interpretation of the FCA, the state and federal governments would need to revise all regulations to distinguish conditions of participation, where noncompliance results only in regulatory action, from requirements that will impact a provider's reimbursement. Petitioner asserts that this distinction is needed to ensure that providers know precisely which violations will impact them financially. *Id*. at 39. Petitioner's construction would lead to an absurd result in which providers prioritize compliance only with the provisions that would impact their bottom line or expose them to FCA liability to the detriment of all other regulatory requirements. Such a bifurcated regulatory scheme undermines incentives for compliance and exposes program beneficiaries to harm.

There is a simpler method that does not require the government to overhaul existing statutes and regulations. Far more workable than Petitioner's categorization of requirements that implicate the FCA and those that do not is the First Circuit's use of the facts in a case to determine materiality. The First Circuit held that determining "whether a given requirement constitutes a precondition to payment" requires a "fact-intensive and context-specific inquiry . . . involving a close reading of the foundational documents, or statutes and regulations, at issue." *Escobar*, 780 F.3d at 513 (citing *New York v. Amgen, Inc.*, 652 F.3d 103, 111 (1st Cir. 2011)). This more reasonable approach permits courts to distinguish isolated technical violations from widespread, long-lasting violations of essential life and safety protections. The First

Circuit further explained that although the supervision requirement was an express condition of payment in the Massachusetts regulations, a condition of payment may also be found in "sources such as statutes, regulations, and contracts" and "need not be expressly designated." *Id*. at 512 (citing *United States ex rel. Hutcheson v. Blackstone Med., Inc*., 647 F.3d 377, 387–88 (1st Cir. 2011))(internal quotation marks omitted). The First Circuit's reasoning in refusing to have categorical divisions between conditions of payment and conditions of participation is sound and should be upheld. *See also New York v. Amgen*, 652 F.3d at 110 (rejecting contention that a claim could only be impliedly false for non-compliance with a legal requirement if that requirement was expressly stated in a statute or regulation, and recognizing importance of the materiality and scienter requirements of the FCA); *United States ex rel. Jones v. Brigham & Women's Hosp*., 678 F.3d 72, 85 (1st Cir. 2012) (rejecting "rigid divisions" to assess FCA liability, noting that the Court "would take a broad view of what may constitute a false or fraudulent statement to avoid foreclose[ing] FCA liability in situations that Congress intended to fall within the Act's scope, and recognizing that the reach of the FCA is not "limitless" but is circumscribed by "strict enforcement of the Act's materiality and scienter requirements")(citing *Hutcheson*, 647 F.3d at 387-88). Requiring rigid categories to distinguish which regulations implicate the FCA will greatly hamper law enforcement efforts and undo years of vital protective work by government agencies and

whistleblowers to address substandard care using the implied certification theory.

The Court should adopt the First Circuit's analysis in which the court evaluates the regulations in a larger context and not in the microscopic manner Petitioner promotes. Through internal compliance programs, providers have an established means of receiving information about potential violations of the law and remedying them. Their failure to create effective compliance programs and promote ethical cultures is their own fault and should not be used as a weapon against the government, whistleblowers and government program beneficiaries.

C. The First Circuit Found That the Supervision Requirements With Which Petitioner Was Out of Compliance Were Conditions of Payment Making It Unnecessary to Evaluate the Viability of the Implied Certification Theory.

This Court need not reach the issue of implied certification, because under the pleading standard of Federal Rule of Civil Procedure 12(b)(6), the allegations and evidence in this case are sufficient to support a claim that Petitioner submitted claims for reimbursement knowing it was out of compliance with an express condition of payment.

There is more than enough evidence to conclude that Petitioner violated an express condition for reimbursement by failing to ensure that all

employees were properly supervised. In accordance with its precedent, the First Circuit held that Respondents survive a Rule 12(b)(6) motion because they demonstrated that "the claims at issue in [the] litigation misrepresented compliance with a material precondition of Medicaid payment such that they were false or fraudulent." *Escobar*, 780 F.3d at 513 (citing *Hutcheson*, 647 F.3d at 377). The court held that "the MassHealth regulations explicitly condition the reimbursement of [satellite facilities'] claims on the clinical director's fulfillment of his regulatory duties . . . ." *Id.* at 514. Among the "plain" duties of a clinical director are "ensuring appropriate supervision" of facility staff. *Id.*; 130 Mass. Code Regs. §429.423(B)(2). Respondents' allegations are more than sufficient to establish that Petitioner's clinical director failed to supervise staff. Petitioner's noncompliance with staffing regulations was rampant, continuous, and corroborated by the Massachusetts Department of Public Health. The Department's investigation deemed Respondents' allegations "valid," noting Petitioner's unlicensed staff of nearly two dozen employees provided mental health services to low-income MassHealth recipients without supervision for up to 16 years. *Id.* at 510. Indeed, Petitioner's clinical director did not even know he was required to supervise his employees. *Id.* at 515. There is no reasonable dispute that Petitioner violated an express condition of payment requiring supervision intended to protect patients from harm.

When Petitioner sought to become a MassHealth provider, it acknowledged that it would

only be entitled to payment when it provides services in accordance with all applicable federal and state requirements. Before a healthcare provider can become a participating provider in the MassHealth program, the provider must sign a MassHealth Provider Contract. 130 Mass. Code Regs. § 450.222. If the provider is accepted into the program, MassHealth agrees to

> pay the provider at rates set by the Massachusetts Executive Office of Health and Human Services or contained in the applicable MassHealth fee schedules for all goods and services *actually* and *properly* delivered to eligible members and properly billed to MassHealth both in accordance with the terms of this Provider Contract and in accordance with all applicable federal and state laws, regulations, rules and fee schedules.

Exec. Office of Health and Human Servs., Commonwealth of Mass., *Provider Contract for Entities* 3 (emphasis added), https://www.mass.gov/eohhs/docs/masshealth/provider-services/forms/gen-16.pdf. Thus, the relationship between MassHealth and Petitioner is first and foremost predicated upon the clear and well-established understanding that Petitioner's services would be reimbursable only if they complied with applicable federal and state statutes.

Taking these facts together, this Court need not even rule on the viability of the implied certification theory. Petitioner, by signing up as a MassHealth provider, committed to complying with all legal requirements as a condition of seeking reimbursement from MassHealth. Therefore, applying the 12(b)(6) standard and considering the evidence and allegations, the dismissal of Respondents' complaint was inappropriate and the First Circuit's decision should be upheld.

II. THE IMPLIED CERTIFCATION THEORY PLAYS A VITAL LAW ENFORCEMENT FUNCTION IN PROTECTING VULNERABLE PEOPLE LIKE NURSING FACILITY RESIDENTS.

Healthcare providers voluntarily participate in state and federally funded healthcare programs, but their participation is conditioned upon their compliance with state and federal law. Nursing facilities must comply with the Federal Nursing Home Reform Amendments (FNHRA) and implementing regulations that set forth minimum standards of care for long-term care facilities that receive federal funding. *See* 42 U.S.C. §§ 1395i-3, 1396r (2012); 42 C.F.R. §§ 483.1-.75 (2015). When healthcare providers knowingly and repeatedly fail to meet these requirements and regulators cannot adequately address the dangerous conditions that result, the FCA's implied certification theory is an essential tool to both address the fraudulent conduct and to compel needed systemic reforms.

In 2014, more than 92% of nursing facilities in the country were cited for deficiencies that impact the health and safety of nursing facility residents. *See* Charlene Harrington et al., Kaiser Family Found., *Nursing Facilities, Staffing, Residents and Facility Deficiencies, 2009 Through 2014* 15 (Aug. 2015), http://files.kff.org/attachment/report-nursing-facilities-staffing-residents-and-facility-deficiencies-2009-through-2014.

The former Director of Health Care for the United States Government Accountability Office (GAO) testified before Congress that "[a] small but significant proportion of nursing homes nationwide continue to experience quality-of-care problems – as evidenced by the almost 1 in 5 nursing homes nationwide that were cited for serious deficiencies in 2006 . . . ." GAO-07-794T, *Nursing Home Reform: Continued Attention is Needed to Improve Quality of Care in Small But Significant Share of Homes* 9 (2007), http://www.gao.gov/new.items/d07794t.pdf. These are "deficiencies that cause actual harm or place residents in immediate jeopardy." *Id*. at 3. In accord with this testimony, a 2007 GAO report on federal enforcement efforts stated: "almost half of the homes we reviewed – homes with prior serious quality problems – continued to cycle in and out of compliance, continuing to harm residents." U.S. Gov't Accountability Office, GAO-07-241, *Nursing Homes: Efforts to Strengthen Federal Enforcement Have Not Deterred Some Homes from Repeatedly Harming Residents* 26 (2007), http://www.gao.gov/new.items/d07241.pdf. The types of deficiencies found in the

facilities that cycled in and out of compliance include inadequate treatment or prevention of pressure sores, resident abuse, medication errors, and employing convicted abusers. *Id*. at 68.[3]

A. Qui Tam Relators Bringing Claims Under the Implied Certification Theory Play an Important Role By Filling the Gap Between Regulators and the Regulated in Settings Like Nursing Facilities.

Whistleblowers play an essential role in uncovering wrongdoing by helping regulators overcome the issue of information asymmetry, wherein the nursing facility or other regulated entity has more information about its internal operations and activities than the regulators. This imbalance in information stifles the government's ability to address wrongdoing. *See* Pamela H. Bucy, *Information as a Commodity in the Regulatory World*, 39 Hous. L. Rev. 905, 940 (2002). Various regulatory processes (e.g., inspections) are used to combat information asymmetry, but they are of limited effectiveness, especially in the nursing facility context. *See, e.g.*, Charles Ornstein & Lena

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[3] The scope of the problem is greater than these federal reports show, as state surveys of compliance with federal quality standards repeatedly understate serious care problems. U.S. Gov't Accountability Office, GAO-08-517, *Nursing Homes: Federal Monitoring Surveys Demonstrate Continued Understatement of Serious Care Problems and CMS Oversight Weaknesses* 11 (2008), http://www.gao.gov/new.items/d08517.pdf.

Groeger, *Two Deaths, Wildly Different Penalties: The Big Disparities in Nursing Home Oversight*, ProPublica (Dec. 17, 2012)(finding large disparities in state enforcement of Centers for Medicare & Medicaid Services regulations), https://www.propublica.org/article.two-deaths-different-penalties-disparities-in-nursing-homes-oversight.

Whistleblowers step in to fill the gap between the regulatory process and hidden wrongdoing, providing "[i]nside information [that] can alert regulators and the public to ongoing or inchoate wrongdoing." Bucy, *supra* at 940. Whistleblowers with a private right of action, i.e., relators, are especially effective at addressing wrongdoing in the nursing facility context, because regulation has been ineffective in stopping continuous, serious noncompliance at many facilities. *See, e.g.* Ctrs. for Medicare and Medicaid Servs., U.S. Dep't of Health and Human Servs., *Special Focus Facilities (SFF) Initiative* 1 (Feb. 18, 2016) (identifying nursing facilities with a "yo-yo" or "in and out" compliance history), https://www.cms.gov/Medicare/Provider-Enrollment-and-CertificationCompliance/Downloads/SFFList.pdf.

Whistleblowers bringing FCA suits using the implied certification theory assist the government in addressing substandard care that the government likely never would have discovered on its own with its traditional regulatory powers and remedies. Yarushka Rivera and countless similarly situated patients at Petitioner's facility received mental health services from 23 unlicensed, unsupervised

therapists for 16 years. *Escobar*, 780 F.3d at 510. These shameful conditions were not uncovered by regulators until Respondent made a formal complaint. *Id*. Petitioner must have been aware that it had created dangerous circumstances for which it was not entitled to bill the government. But without the Respondents demanding an investigation, the conditions at Arbour would still be concealed. *Id*. at 515.

B. Global Settlements from Cases Relying on the Implied Certification Theory Have Greatly Improved Conditions in Nursing and Other Healthcare Facilities.

The false certification theories are essential legal tools upon which the government and whistleblowers have depended when bringing FCA cases to specifically address substandard care in settings like nursing facilities.[4] The express certification theory applies to claims where the falsity is demonstrated on the face of the claim. By contrast, under the implied certification theory, the defendant's claims are false not because of any false statements on their face but because they do not

[4] The government and relators also rely upon the worthless services theory to challenge substandard care. *See, e.g., United States ex rel. Mikes v. Straus*, 274 F.3d 687, 702 (2d Cir. 2001) ("A worthless-services claim asserts that the knowing request of federal reimbursement for a procedure with no medical value violates the False Claims Act . . . ."); *United States ex rel. Lee v. SmithKline Beecham, Inc.*, 245 F.3d 1048, 1053 (9th Cir. 2001) (noting worthless-services theory based on "seeking and receiving payment for medically worthless tests").

satisfy state and federal minimum standards, which are fleshed out in regulations imposing specific requirements necessary for items or services to be reimbursable. The implied certification theory is an entirely valid basis for FCA liability and one which numerous other courts of appeals have expressly adopted.

According to the Tenth Circuit, "the key attribute of implied false certification claims – and what most clearly differentiates them from express-false-certification claims – is that the payee's request for payment lacked an express certification." *United States ex rel. Lemmon v. Envirocare of Utah, Inc.*, 614 F.3d 1163, 1169 (10th Cir. 2010). The Tenth Circuit continued, "[t]he pertinent inquiry for [implied false certification] claims is not whether a payee made an affirmative or express false statement, but whether, through the act of submitting a claim, a payee knowingly and falsely implied that it was entitled to payment." *Id.*

A particularly instructive implied certification analysis is found in *United States ex rel. Sanchez-Smith v. Tulsa Reg'l Med. Ctr., LLC*, 754 F. Supp. 2d 1270 (N.D. Okla. 2010). That case involved a Medicaid-funded provider that failed to provide active treatment to minors in inpatient psychiatric settings. *Id.* at 1274-75. Active treatment was defined to require that the treatment staff meet with patients for a minimum number of hours per week. *Id.* at 1277-78. The inpatient facility staff consistently failed to meet the active treatment requirement, but submitted claims for

reimbursement as if they were entitled to payment. *Id*. at 1272. The Oklahoma court distinguished its role in evaluating whether the facility met the active treatment requirement from the Second Circuit's role in evaluating the spirometry tests in *Mikes v. Straus*. *Id*. at 1293 (citing 274 F.3d 687, 701-02 (2d Cir. 2001)). In order to evaluate whether the *Mikes* spirometry tests were of a "quality meeting professionally recognized standards," the court would have had to "step outside" its area of competence and "apply a qualitative standard measuring the efficacy of those procedures." *Id*. In *Sanchez-Smith*, by contrast, "the active treatment requirements allegedly violated [were] objective and/or quantitative because they [were] simply weekly minimum therapy requirements . . . ." *Id*. In other words, the regulatory standard in *Sanchez-Smith,* like the supervision requirement in *Escobar*, was "objective" and did "not present difficulties in application." *Id*.

Similarly, in *United States v. Sci. Applications Int'l Corp*., the D.C. Circuit held that a contractor could be liable under the FCA for submitting invoices for services provided under a contract while knowing that it was violating a material contractual provision prohibiting conflicts of interest. 626 F.3d 1257, 1261 (D.C. Cir. 2010). Characterizing its holding as an application of the "implied certification" theory of liability, the court hypothesized the facts to a company that was contractually obligated to supply gasoline to the government with an octane rating of 91 or higher but instead supplied gasoline that had an octane rating of only 87. *Id*. at 1269. The company failed to disclose to the government that it

had failed to meet the standard required by the contract. *Id*. Even if the company simply submitted monthly invoices that made no statements about the octane of the gasoline supplied (and did not expressly and falsely represent it was in compliance), the D.C. Circuit concluded that the invoices would be false so long as the government could demonstrate that the octane level was a material element of the contract. *Id*.

i. The government and whistleblowers need the implied certification theory to enforce the FCA in cases related to nursing facilities that endanger vulnerable people by flagrantly and regularly disregarding statutory and regulatory requirements.

By examining several instances in which the FCA's implied certification theory was used to address substandard care, one can understand that the regulatory enforcement processes would have been inadequate to address the kind of widespread, chronic noncompliance that these cases illustrate. The positive impact of these cases on vulnerable people is confirmed by looking at some recent settlements between nursing facility corporations and the federal and state governments. The following cases are just a portion of the important work that the government and whistleblowers do to identify and address providers' long-lasting, knowing and flagrant noncompliance with well-established minimum provider standards as the basis for demonstrating fraud. These cases illustrate the

manner in which the implied certification theory can be used to enforce the FCA when nursing facilities or other healthcare providers refuse to meet basic life-sustaining regulatory standards year after year. If this Court undermines the viability of the implied certification theory, much of this vital work will disappear and the long-term impact on vulnerable people will be immense.

For example, in 2014, the federal government and the State of Maryland settled a lawsuit against Foundation Health Services, Inc. (FHS), in which FHS paid $750,000 to resolve allegations that it submitted false claims for materially substandard and/or worthless skilled nursing facility services. Press Release, U.S. Attorney's Office, Dist. of Md., U.S. Dep't of Justice, *Nursing Home Chain To Pay $750,000 To Resolve False Claims Act Allegations* (June 13, 2014), https://www.justice.gov/usao-md/pr/nursing-home-chain-pay-750000-resolve-false-claims-act-allegations. FHS is a Louisiana not-for-profit company that owns and manages nine nursing facilities in five states. *Id.* According to the government, from 2006 to 2010, some of the skilled nursing services provided at several FHS nursing facilities were materially substandard and/or worthless because they failed to meet minimum state and federal requirements for nursing facility care. *Id.* Specifically, the government alleged that FHS submitted claims implying it was in compliance with all quality of care standards, but in fact, it was not in compliance with many fundamental requirements. For example, FHS failed to

a) follow appropriate fall protocols;
b) follow appropriate pressure ulcer and infection control protocols;
c) properly administer medications to avoid medication errors;
d) appropriately provide for activities of daily living including bathing, monitoring, feeding and supervising for some residents;
e) provide appropriate mental health treatment;
f) answer call lights promptly;
g) employ a sufficient number and skill-level of nursing staff to adequately care for the residents; and
h) provide a habitable living environment, adequate equipment and needed capital expenditures.

Id. As a result of this settlement, FHS closed one of its facilities with the most egregious violations and agreed that the remaining facilities would be under a five-year Corporate Integrity Agreement (CIA) with the OIG of the U.S. Department of Health and Human Services. *Id*.; infra at 24-27 (discussing impact of CIAs).

In 2013, the United States and the State of Georgia reached a settlement with Golden Living of Plano, Texas to resolve allegations brought under the implied certification theory. *See* Press Release, U.S. Attorney's Office, N.D. Ga., U.S. Dep't of Justice,

Golden Living Nursing Homes Settle Allegations Of Substandard Wound Care (Jan. 2, 2013), https://www.justice.gov/usao-ndga/pr/golden-living-nursing-homes-settle-allegations-substandard-wound-care. Golden Living agreed to pay $613,300 to resolve allegations that from 2006 to 2011, the company "placed at risk the life and health of individuals who were entrusted to its care" by failing to provide adequate wound care services to its nursing home residents. *Id.* The relator in the case was a doctor who had practiced at one of the Golden Living facilities where there was only one wound care specialist for 230 patients. Complaint at 46, *United States ex rel. Micca v. GGNSC Holdings, LLC* (N.D. Ga. May 23, 2012)(No. 1:10-CV-1055-ODE). The Relator contended that he made repeated attempts to warn of the substandard wound care at Golden Living's facility, but without result. *See id.* at 34, 42. The relator alleged that "the nursing care, wound care, medication administration, daily monitoring, and other issue . . . all of which were the responsibility of Defendants and their agents was either not rendered at all or was only rendered in contravention of the rules and regulations of Medicare and Medicaid programs . . . ." *Id.* at 71-72.

The relator described how the facility failed to meet statutory and regulatory requirements by laying out the harm that befell several of the facility residents. One resident, a quadriplegic who was totally unable to care for herself, was dependent on nursing staff to assist her with tube feeding for hydration and nutrition. *Id.* at 35. Although it was well-known that her gastrostomy tube needed to be

carefully handled, the facility staff traumatically removed it again and again leading to hospitalizations. *Id*. at 36. On top of that, while in the facility's care, the resident developed a wound on the ball of her foot which required daily care to heal. *Id*. at 37-38. Despite documenting that they knew how to position her to accommodate the wound's healing, staff instead positioned the patient in a manner that applied pressure to the wound, causing it to expand and become badly infected, eventually causing her death. *Id*. at 38-39. Relator also described another victim whom the facility staff failed to treat in accordance with minimum standards, even though they were well aware that he had acquired a serious pressure ulcer on his foot during his stay at the facility. *Id*. at 42. As a result, the wound worsened considerably over a two-week period, leading to gangrene. *Id*. The patient required a mid-foot amputation to prevent the gangrene from spreading from his foot to the rest of his body. *Id*. Shortly after the amputation, the patient died of a heart attack. *Id.*

Less than a year after the complaint was filed, Golden Living settled with the federal and state governments, paying a fine and agreeing to enter into a CIA with the OIG of the Department of Health and Human Services. *See* Press Release, U.S. Attorney's Office, N.D. Ga., U.S. Dep't of Justice (Jan. 2, 2013). The agreement covers six of the defendant's facilities in the Atlanta area and requires that the chain work with an independent monitor appointed by the government to verify that the facilities' residents receive appropriate care. *Id*.

In 2015, the federal government settled another lawsuit that alleged that the owners, operators, and managers of two nursing facilities in Watsonville, California submitted false claims to the Medicare and Medi-Cal programs. The government alleged that the care at the facilities was materially substandard and brought the litigation relying on the implied certification theory. Complaint at 1-3, *United States v. Arba Grp. et al.*, (N.D. Cal. Aug. 29, 2014)(No. 14-3946). Specifically, the complaint alleges that between 2007 and 2012, the defendants persistently overmedicated elderly and vulnerable residents of the nursing facilities, causing infection, sepsis, malnutrition, dehydration, falls, fractures, pressure ulcers, and for some residents, premature death. *Id.* The complaint described how the defendants failed to address dangerous deficiencies that had been identified by the California Department of Public Health related to the excessive and inappropriate use of psychotropic and other drugs. *Id.* at 14-19. The flagrant violations resulted in unnecessary falls, deterioration and even the death of residents at two of the corporations' facilities. *Id.* at 21.

ii. Implied certification is often the legal theory underpinning cases that result in Corporate Integrity Agreements which compel recalcitrant providers to undertake life-saving reforms.

The impact of FCA lawsuits on the quality of healthcare is even greater when the defendant enters

into a CIA as part of a global settlement. *See* Office of Inspector Gen., U.S. Dep't of Health and Human Servs., Corp. Integrity Agreements, http://www.oig.hhs.gov/fraud/cias.asp (identifying companies that have previously executed CIAs with OIG). The OIG negotiates compliance obligations with healthcare providers and other entities as part of the civil settlement of FCA litigation. *Id*. Usually a company agrees to adhere to a CIA for five years in exchange for the OIG's agreement not to seek exclusion of that healthcare provider from participation in Medicare, Medicaid, and other federal healthcare programs. *Id*. A key component of the quality-of-care CIAs — many of which emerge as a result of cases that are predicated upon the implied certification theory — is the appointment of an independent quality monitor who is selected by the OIG to monitor the performance of the facility or chain.

In addition to the independent quality monitor, quality-of-care CIAs also usually include the following means through which the corporation will build its internal quality assurance program: a) appointment of a compliance officer at a relatively high level in the corporation; b) creation of a compliance committee; c) development of written standards and policies; d) implementation of a comprehensive employee training program; e) creation of a system through which the corporation will ensure that it is monitoring the claims it submits to the government for accuracy and quality of the underlying services; f) establishment of a confidential disclosure program so that whistleblowers can safely and confidentially identify violations of law or safety

concerns; g) provision of a means through which the corporation will do background checks to restrict employment of persons who are not appropriate to work with vulnerable people; and h) implementation of a reporting system whereby the corporation will report payment issues, reportable events, and ongoing investigations or other violations of the law to the OIG. *See, e.g.*, Office of Inspector Gen., Dep't of Health and Human Servs., *Corporate Integrity Agreement Between The Office of Inspector General of Department of Health and Human Services and GGNSC Holdings, LLC et al.*, 4-39 (Dec. 2012), http://www.oig.hhs.gov/fraud/cia/agreements/Golden_LivingCenter_12212012.pdf.

In 2009, the OIG reviewed 15 chain-wide CIAs that it entered into with corporate nursing facility chains between 2000 and 2005 to evaluate whether these agreements have had a positive impact on the quality of the services provided after the execution of the CIA and the settlement of the FCA lawsuit. Office of Inspector Gen., Dep't of Health and Human Srvs., OEI-06-06-00570, *Nursing Home Corporations Under Quality of Care Corporate Integrity Agreements* at i (Apr. 2009), https://oig.hhs.gov/oei/reports/oei-06-06-00570.pdf. According to the report, "all 15 corporations enhanced quality of care structures and processes to meet the CIA requirements. Corporate representatives from each corporation cited positive effects of their CIAs. Although all corporations were ultimately responsive to their quality monitors' guidance and valued their input, three corporations were initially resistant until OIG intervened." *Id.* at ii. Unlike standard

regulatory enforcement actions, "a provider's continued failure to address quality of care [through compliance with the CIA] may warrant opening new investigations by OIG" and potentially could result in the provider's exclusion from participation in federal healthcare programs. *Id.* at iii.

As the discussion above demonstrates, the implied certification theory under the FCA is a catalyst for reforming providers that have been continuously and flagrantly out of compliance with minimum safety protections. Regulatory enforcement mechanisms are demonstrably inadequate to effectively address the dangers that such noncompliance poses to vulnerable people. The government and whistleblowers depend on the availability of all tools to address the widespread disregard of these protections, but especially the implied certification theory.

CONCLUSION

For the foregoing reasons, AARP respectfully submits that the decision of the Court of Appeals for the First Circuit should be affirmed.

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