No. 15-10838-B

IN THE UNITED STATES COURT OF APPEALS
FOR THE ELEVENTH CIRCUIT

_____

UNITED STATES and STATE OF FLORIDA
ex rel. CHARLES ORTOLANO,
Plaintiffs-Appellants,

v.

AMIN RADIOLOGY INC. d/b/a CITRUS DIAGNOSTIC CENTER
and d/b/a DUNNELLON OPEN MRI,
Defendant-Appellee.

_____

On Appeal from the United States District Court For the
Middle District of Florida, Case No. 5:10-cv-00583-WTH-TBS

_____

BRIEF OF AMICI AARP AND CENTER FOR MEDICARE ADVOCACY, INC. IN SUPPORT OF PLAINTIFFS-APPELLANTS

_____

Maame Gyamfi

On the Brief
Kelly Bagby
William Thanhauser
AARP Foundation Litigation
601 E Street, NW
Washington, DC 20049
Phone: (202) 434-6291

Counsel for Amici

United States ex. rel. Ortolano v. Amin Radiology, No. 15-10838-B

CERTIFICATE OF INTERESTED PERSONS AND CORPORATE DISCLOSURE STATEMENT

AARP

The Internal Revenue Service has determined that AARP is organized and operated exclusively for the promotion of social welfare pursuant to Section 501(c)(4) (1993) of the Internal Revenue Code and is exempt from income tax. AARP is also organized and operated as a non-profit corporation pursuant to Title 29 of Chapter 6 of the District of Columbia Code 1951.

Other legal entities related to AARP include AARP Foundation, AARP Services, Inc., Legal Counsel for the Elderly, and AARP Insurance Plan, also known as the AARP Health Trust.

AARP has no parent corporation, nor has it issued shares or securities.

Center for Medicare Advocacy, Inc. (CMA)

The Internal Revenue Service has determined that CMA is organized and operated exclusively for the promotion of social welfare pursuant to Section 501(c)(3) (1993) of the Internal Revenue Code and is exempt from income tax. CMA is organized and operated as a non-profit corporation incorporated in the State of Connecticut. CMA has no other legal entities related to it and has no parent corporation, nor has it issued shares or securities.

United States ex. rel. Ortolano v. Amin Radiology, No. 15-10838-B

Further, Counsel for Amici AARP and CMA certifies that, to the best of her knowledge, the Certificate of Interested Persons and Corporate Disclosure Statement included in appellant's opening brief is complete. In addition to the individuals and entities listed in that certificate, the following counsel for Amici also have an interest in this case under 11th Cir. Rule 26.1:

1. Maame Gyamfi
2. Kelly Bagby
3. William Thanhauser

July 8, 2015

/s/ Maame Gyamfi
Maame Gyamfi

Counsel for Amici

TABLE OF CONTENTS

PAGE

TABLE OF AUTHORITIES

Cases

Statutes

Legislative History

Other Authorities

STATEMENT OF THE ISSUE[1]

Whether sufficient evidence existed at trial to support a legal finding that Defendant filed false claims for reimbursement for PET/CT procedures performed by general radiographers, who were unsupervised, unqualified, unlicensed, and untrained to do so, in violation of Florida law and the Department of Health and Human Services' regulatory standard to be "reasonable and necessary" and thus reimbursable (42 U.S.C. § 1395y(a)(1)(A) (2003), services must be performed by qualified personnel and must have "the required level of supervision" (*see* 42 C.F.R. § 410.32(b)(1) (2003) and 42 C.F.R. § 411.15(k)(1)(2003)), including "the training of the nonphysician personnel who actually perform the diagnostic procedure," which training is "the continuing responsibility of the physician." 42 C.F.R. § 410.32(b)(3)(i) (2003).

INTEREST OF THE AMICI CURIAE

AARP

AARP is a nonprofit, nonpartisan organization, with a membership that helps people turn their goals and dreams into real possibilities, strengthens

[1] Amici certify that no party or party's counsel authored this brief in whole or in part, or contributed money that was intended to fund the brief's preparation or submission, and further certifies that no person, other than AARP and its members, contributed money intended to prepare or submit this brief. Fed. R. App. P. 29(c)(5). Both parties have consented to the filing of this brief.

communities and fights for the issues that matter most to families such as healthcare, employment and income security, retirement planning, affordable utilities and protection from financial abuse. Through education, advocacy and service, AARP seeks to enhance the quality of life for all by promoting independence, dignity, and purpose. As the country's largest membership organization, AARP advocates for access to affordable healthcare and for controlling costs without compromising quality.

Center for Medicare Advocacy, Inc.

Founded in 1986, the Center for Medicare Advocacy, Inc. is a non-profit public interest law organization that represents older and disabled people throughout the United States. The Center works to advance fair access to Medicare, Medicaid, and quality health care through individual representation, education, policy analysis, administrative advocacy, and litigation. A crucial component of this effort is ensuring that the elderly and disabled are able to obtain accurate diagnoses for care and treatment decisions.

SUMMARY OF ARGUMENT

The district court erred as a matter of law by directing a verdict for Appellee thereby releasing it from all liability despite Appellee's flagrant disregard of Medicare's requirement that its services be "reasonable and necessary" to be reimbursable by the federal government. The Medicare and state law requirements

that the personnel furnishing health care services be qualified to perform the service not only protects the government from fraud, but also ensures that the public is protected from substandard and unsafe care.

The outcome of this litigation will particularly impact older people because they utilize a great deal of health care services and depend on the financial viability of the Medicare program to have access to quality services. Their high utilization rate puts older people at greater risk of harm resulting from poor medical care. In addition, as regular consumers of healthcare services, older people particularly depend on accurate medical diagnostic procedures—e.g., MRI, PET, and CT scans—to make medical care and treatment decisions.

The district court committed reversible error when it directed a verdict in favor of Appellee, as it relied on a tortured analysis of Medicare rules and the requirements of the False Claims Act (FCA). The court's erroneous determination that a finding of a "condition of payment" must be established before a claim is determined to be false is not found anywhere in the FCA. Moreover, the court's decision eviscerates the specific quality protections provided by Medicare requirements and the FCA.

Whistleblowers are vital to the enforcement of the FCA and the lawsuits that they bring play a significant role in uncovering fraud against the government and vulnerable populations. Whistleblowers are uniquely situated to uncover

healthcare fraud that may be hidden from healthcare reimbursement claims processors and law enforcement because they normally work in and among defrauding parties, and thus can uncover and expose fraud that might not otherwise be found. Here, the whistleblower uncovered that false claims were submitted for services performed by unqualified personnel. Thus the jury's verdict, obtained after a full trial, should be upheld.

ARGUMENT

I. THE COURT'S DECISION WILL DIRECTLY IMPACT OLDER PEOPLE BECAUSE OLDER PEOPLE USE THE GREATEST AMOUNT OF HEALTH CARE SERVICES AND DEPEND ON MEDICARE TO HAVE ACCESS TO QUALITY CARE.

The outcome of this litigation will disproportionately impact older people because they utilize a great deal of health care services and depend on the financial viability of the Medicare program to have access to needed health care services. *See* Ctrs. for Medicare & Medicaid Servs., *NHE Fact Sheet*, http://goo.gl/pGX0wd (last modified Dec. 3, 2014) (finding that health care spending for persons 65 and older is three times higher than spending per "working-age" person). In 2010, adults aged 65 and older constituted only thirteen percent of the population, yet accounted for thirty-four percent of health care spending. *Id.* This high proportion of health care usage applies to both chronic and acute treatment. Adults aged 65 and older are twenty percent more likely than adults aged 18 to 44, and ten percent more likely than adults aged 45 to 64, to have visited a health professional in the

past year. *See* Ctrs. for Disease Control & Prevention, *Summary Health Statistics for U.S. Adults: National Health Interview Survey, 2012*, at 95 tbl. 33 (2014), http://goo.gl/1abcJF. Similarly, adults aged 65 and older are three times more likely than adults aged 45 to 64, and four times more likely than persons aged 15 to 44, to receive in-patient hospital treatment. Ctrs. for Disease Control & Prevention, *National Hospital Discharge Survey: 2010 Table – Number and Rate of Hospital Discharges* (2010), http://goo.gl/16Oy9w.

Older Americans' high utilization rate for healthcare services puts them at greater risk of harm resulting from medical care ("adverse events"). Thirteen percent of Medicare beneficiaries hospitalized in 2008 experienced a serious adverse event—e.g., an event prolonging their hospitalization, requiring life-sustaining intervention, or resulting in permanent harm or death—during their stay. *See* Office of the Inspector Gen., Dep't of Health & Human Servs., OEI-06-09-00090, *Adverse Events in Hospitals: National Incidence Among Medicare Beneficiaries*, at ii (2010), https://goo.gl/opFO6V. Relative to the rest of the population, adults aged 65 and older are more likely to be misdiagnosed or underdiagnosed (receive a delayed diagnosis) by doctors, and twice as likely to be victims of serious medical error. Jeffrey M. Rothschild & Lucian L. Leape, AARP Pub. Policy Inst., *The Nature and Extent of Medical Injury in Older Patients* 13,

23, 26, 29 (2000).[2] Altogether, older Americans' high level of interaction with the healthcare system imposes significant institutional and individual financial costs and exposes them to potential serious physical harm.

Eighty-six percent of Americans aged 65 and older suffer from at least one chronic condition; from this population, ninety-four percent visit a health care professional at least once annually, and twenty percent visit a health care professional ten or more times annually. Brian W. Ward et al., *Multiple Chronic Conditions Among US Adults: A 2012 Update*, Preventing Chronic Disease, Apr. 17, 2014, at 1-2, http://goo.gl/IDpObk; Ctrs. for Disease Control & Prevention, *Summary Health Statistics for U.S. Adults: National Health Interview Survey, 2012*, at 93 tbl. 32 & 95 tbl. 35 (2014), http://goo.gl/1abcJF. Sixteen percent of adults aged 65 and older receive acute hospital treatment annually, with average hospitalizations lasting almost six days. *See* Ctrs. for Disease Control & Prevention, *Health, United States, 2013*, at 294 tbl. 94 & 300 tbl. 95 (2014) (data for 2013), http://goo.gl/qhGacC. In terms of diagnostic services, Medicare patients underwent over 3.3 million CT scan procedures and over 1.1 million MRI scan procedures. *See* MedPAC, *A Data Book: Health Care Spending and the Medicare Program* 101 tbl. 7-13 (2014), http://goo.gl/uD56wI.

---

[2] These medical errors also cost older Americans $350,000, on average, in productivity loss. Jon Shreve et al., *The Economic Measurement of Medical Errors* 16 (2010), https://goo.gl/qpdJK6.

As regular consumers of healthcare services, older people depend services which aid is securing an accurate medical diagnoses, such as the services at issue here. Individuals rely on diagnostic procedures—e.g., MRI, PET, and CT scans—to make medical care and treatment decisions. *See* Chad Cook, *The Lost Art of the Clinical Examination: An Overemphasis on Clinical Special Tests*, 18 J. Manual & Manipulative Therapy 3, 3 (2010), http://goo.gl/doj3s1 (finding that clinicians increasingly rely on diagnostic imaging when examining patients). Imprecise or incorrect diagnoses have significant financial and health consequences—each diagnostic error costs the health care system almost $400,000, and overall, diagnostic errors account for 40,000 to 80,000 hospital deaths annually. Paul Cerrato, *Reducing the Costs of Misdiagnosis*, Healthcare Fin., Aug. 14, 2013, http://goo.gl/0JIZtt. As discussed above, older people routinely interact with the healthcare system and, as part of this, undergo diagnostic procedures with exceptional regularity. *See* MedPAC, *A Data Book: Health Care Spending and the Medicare Program*, 101 tbl. 7-13 (2014), http://goo.gl/uD56wI (finding that, in 2012, Medicare beneficiaries underwent over 3.3 million CT and over 1.1 million MRI scan procedures).

Thus, older people are particularly at risk when the safety and accuracy of diagnostic procedures are compromised as the district court's decision would allow. Medicare's requirement that services be "reasonable and necessary,"

including that the personnel furnishing health care services be qualified to perform the service, ensures that older people are protected from substandard and unsafe care. *See* 42 U.S.C § 1395y(a)(1)(A). Minimizing that requirement by failing to recognize that Medicare reimbursement is contingent on qualified personnel providing the health care services will have a devastating impact on the quality of care older people receive.

II. THE DISTRICT COURT'S RULING EVISCERATED THE GOALS OF THE FALSE CLAIMS ACT BY ERRONEOUSLY FINDING THAT APPELLEE'S CLAIMS WERE NOT FALSE BECAUSE THE STATUTORY SAFETY PROTECTIONS UNDER FLORIDA LAW WERE NOT CONDITIONS OF PAYMENT.

The district court erred as a matter of law when it directed a verdict in favor of Appellee, as it relied on a tortured analysis of Medicare rules and the requirements of the False Claims Act (FCA), 31 U.S.C. §§ 3729-33. To reach its decision, the court improperly relied on Appellee's contention that compliance with the state statute that governed the licensing of personnel authorized to perform PET/CT scans was not a condition of payment for Medicare or Medicaid. First, the court recognized that it was undisputed that Appellee Amin Radiology permitted general radiographers to perform PET/CT scans and that general radiographers were not qualified to perform such procedures according to the Florida licensure law. *U.S. ex rel. Ortolano v. Amin Radiology*, No. 5:10-cv-583-OC-PRL, 2015 U.S. Dist. LEXIS 9724, at *10-11 (M.D. Fla. Jan. 28, 2015).

However, the court then rejected the Appellant's argument that noncompliance with the safety and qualification protections in the state licensure law rendered the PET/CT scans unreasonable and unnecessary, and therefore, not reimbursable by the federal government. *Id.* at 18. Instead, the court concluded that these state licensing requirements governed only whether a health care provider could "participat[e]" in federal health care programs, not whether the health care provider could receive reimbursement. *Id.* at 27-28.

The district court's flawed interpretation of the requirements to receive reimbursement from Medicare and Medicaid eviscerates the protection and incentives for compliance that the FCA provides. A central purpose of the FCA is to ensure that health care entities provide good and safe quality of care – an underpinning of which is that the health care provider meets the basic state licensure requirements before it places the public at risk by allowing untrained and unqualified workers to perform services. The court's decision here is erroneous because its reliance on finding a "condition of payment" before a claim is determined to be false is not found anywhere in the FCA. Moreover, the court's decision overturning the jury erodes the specific quality protections that Medicare and the FCA provide.

A. The FCA Does Not Support the District Court's Reliance On A Separate "Condition of Payment" Standard To Determine That a Claim Is False Or Fraudulent.

The district court's most egregious error is reading into the FCA a "condition of payment" versus "condition of participation" standard that does not exist. The FCA is the "primary litigative tool for the recovery of losses sustained as the result of fraud against the government." *Avco Corp. v. United States Dep't of Justice*, 884 F.2d 621, 622 (D.C. Cir. 1989). The FCA, in pertinent part, makes it a crime for any person or organization to knowingly file a false claim regarding Medicare, Medicaid, or any federal health care program, whether directly, through insurance or otherwise. 31 U.S.C. § 3729(a) (2012). The FCA carries penalties of $5,500 to $11,000 per false claim, and allows recovery of treble damages. 28 C.F.R. § 85.3(a)(9) (2014). The FCA also contains a whistleblower component that permits individuals and entities to report violations of the FCA to the government. 31 U.S.C. § 3730(b)(1) (2012). These whistleblowers, referred to as "relators," report these violations through a lawsuit known as a *qui tam* action, such as in the present case. *Id*.

The Supreme Court has explained that when Congress enacted the FCA, it wrote expansively meaning 'to reach all types of fraud, without qualification, that might result in financial loss to the Government.'" *Cook Cnty. v. U.S. ex rel. Chandler*, 538 U.S. 119, 129 (2003) (quoting *U.S. v. Neifert-White Co.*, 390 U.S.

228, 232 (1968)); *see U.S. ex rel. Loughren v. Unum Grp.*, 613 F.3d 300, 305-06 (1st Cir. 2010) ("The FCA covers all fraudulent attempts to cause the government to pay out sums of money") (quoting *U.S. ex rel. Conner v. Salina Regional Health Ctr., Inc.*, 543 F.3d 1211, 1217 (10th Cir. 2008).

To bring a claim under the FCA, relators need only satisfy two elements: 1) the relators must plead with sufficient specificity that the defendant knowingly submitted false claims to the government seeking reimbursement; and 2) the relators must establish that the claims at issue rise to the level of a "false claim" because the underlying wrongdoing or non-compliance was "material" to the government's reimbursement decision. *U.S. ex rel. Atkins v. McInteer*, 470 F.3d 1350, 1357 (11th Cir. 2006). Not every violation of a health care regulation rises to the level of a FCA claim. Rather, the relators must plead that a violation of a health care regulation, compliance with which was implicit in the submission of a claim for reimbursement, was *material* to the government's reimbursement decision. *See Urquilla-Diaz v. Kaplan Univ.*, 780 F.3d 1039, 1056 (11th Cir. 2015). Nowhere in the FCA is there an additional requirement that relators establish that the claim is based on a "condition of payment" versus a "condition of participation."

It is undisputed that Appellee knew it submitted hundreds of claims for services furnished by staff that did not meet the state qualification requirements.

Therefore, Appellee knew it was submitting claims for services despite being woefully out of compliance with the law. Nonetheless, Appellee incorrectly argues that such non-compliance was not material to the decision to pay it for its services. Appellee states that its non-compliance related to a condition of participation that allowed it to be a Medicare provider, but not to a condition of payment that Medicare would require in deciding to reimburse the provider. *U.S. ex rel. Ortolano v. Amin Radiology,* No. 5:10-cv-583-OC-PRL, 2015 U.S. Dist. LEXIS 9724, at *28-29.

Courts have correctly recognized that whether a requirement is a condition of payment or participation is often "a distinction without a difference." *See, e.g.*, *U.S. ex rel. Hendow v. U. of Phx.*, 461 F.3d 1166, 1176 (9th Cir. 2006); *U.S. ex rel. Conner v. Salina Reg. Health Ctr., Inc.* (quoting *Hendow* and explaining that "some regulations or statutes may be so integral to the government's payment decision as to make any divide between conditions of participation and conditions of payment a 'distinction without a difference'"); *U.S. ex rel. Tyson v. Amerigroup Ill., Inc.*, 488 F. Supp. 2d 719, 726 (N.D. Ill. 2007) (quoting *Hendow* and declaring that "'if we held that conditions of participation were not conditions of payment, there would be no conditions of payment at all'"). Indeed, it is illogical to create an artificial line between conditions of participation and conditions of payment when proving eligibility to participate as a health care provider in a

government-funded program is necessarily the first condition that must be met before a claim for payment can be submitted to Medicare or Medicaid.

This Court should adhere to the rule of law applied by other Circuits that recognized that a claim may be false or fraudulent due to an implied representation of compliance where reimbursement is not tied to compliance in the text of the statute or regulation. For example, the D.C. Circuit has rejected any "condition of payment" limitation on FCA liability noting such a "legal requirement [was] found nowhere in the statute's language." *U.S. v. Sci. Applications Int'l Corp.*, 626 F.3d 1257, 1269 (D.C. Cir. 2010) ("*SAIC*"). The *SAIC* court acknowledged that by limiting FCA analysis to regulations that constitute a "condition of payment," "one would foreclose FCA liability in situations that Congress intended to fall within the Act's scope." *Id.* at 1268. The *SAIC* court's conclusion that the scope of the FCA should be assessed broadly, and without regard to categorical divisions not found in the text of the FCA, has been reaffirmed repeatedly. *See, e.g., New York v. Amgen, Inc.*, 652 F.3d 103, 111 (1st Cir. 2011) (rejecting a 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).

The First Circuit in *U.S. ex rel. Hutcheson v. Blackson Med. Inc.*, adopted the analysis of *SAIC*, and directed a return to the text of the FCA to assess whether

a claim for reimbursement was *knowingly* submitted, and whether the allegedly false claim was *material* to the reimbursement decision. 647 F.3d 377, 387-89 (1st Cir. 2011). More recently, in *U.S. ex rel. Escobar v. Universal Health Servs.*, the First Circuit faced the terrible harm that can ensue when a Medicaid or Medicare provider attempts to secure reimbursement for the work of unlicensed and inadequately supervised staff.[3] 780 F.3d 504 (1st Cir. 2015). The relator's daughter Yarushka Rivera—a recipient of MassHealth benefits—was assigned various people who held themselves out as treating professionals at Arbour Counseling Services. *Id.* at 509. After years of being seen by a variety of what was later discovered to be unlicensed people billing the government as if they were licensed psychiatrists, social workers and others with prescribing privileges; Yarushka was prescribed a dangerous drug for bipolar disorder. *Id.* She was not in fact suffering from bipolar disorder and ended up in the hospital where she continued to suffered seizures and died. *Id.* After her death, Yarushka's parents

[3] The District Court here summarily disregarded the inherent danger of its decision when it underscored the fact that there was no evidence that the PET/CT scans carried out by Appellee were "medically faulty or unreliable" or that "any patient was ever injured or harmed in any way by the manner in which the scans were carried out." *U.S. ex rel. Ortolano v. Amin Radiology*, No. 5:10-cv-583-OC-PRL, 2015 U.S. Dist. LEXIS 9724, *11 at n. 4. The court here confuses facts that demonstrate "good fortune" for legally significant facts. Nothing in FCA requires that patients experience actual harm in connection with the submission of fraudulent claims. To raise the bar for a relator to demonstrate that patients must suffer from the Appellee's cavalier disregard of licensure statutes undermines the clear intent of the FCA.

asked the state to review the facility, and the state, after comprehensively reviewing Arbour's personnel files, concluded that "23 therapists were not licensed for independent practice and also ... were not licensed in their discipline." Also, although "all twenty-three therapists required clinical supervision, there was no documentation to show that any had received such supervision prior to January 2012, despite having been hired as early as 1996." *Id.* at 510. Yarushka's distraught parents sued under the FCA. *Id.* The district court eventually dismissed the case finding that the failure to comply with the Massachusetts regulations around qualifications of treating professionals was not a condition of payment but rather merely a condition of participation. *Id.* at 511.

On appeal, the First Circuit held that taking a broad view of FCA is essential to reach all types of fraud that might result in a financial loss to the government. *Id.* at 512. The First Circuit rejected the theory advanced by the district court here, finding that it would "create artificial barriers that obscure and distort [the statute's] requirements." *Id*. The court rejected the idea that "conditions of payments" need to be expressly designated and instead adopted a fact-intensive and context-specific inquiry in linking compliance to eligibility for payment. *Id.* at 512-13.

Applying the logic of the above circuits to this case reveals that Appellee's claims were false under the FCA as no dispute exists that the staff furnishing the

services did not meet requirements set forth in state law. Any ruling that attempts to separate that fact by creating divisions between "conditions of payment" and "conditions of participation" ignores the purpose of the FCA and the Medicare requirements.

B. Medicare's "Reasonable and Necessary" Standard for Reimbursement Necessarily Depends on the State's Definition of the Qualifications Necessary To Provide Reimbursable Services.

The district court improperly rejected Relator's arguments that Medicare Part B covers the costs of physician services, supplies and tests, and "prohibits reimbursement of procedures or services unless they are 'reasonable and necessary' for the diagnosis and treatment for illness or injury." *U.S. ex rel. Ortolano v. Amin Radiology*, 2015 U.S. Dist. LEXIS 9724, *10 (citing 42 U.S.C. § 1395y(a)(1)(A)). Specifically, the court rejected the Appellant's contention that because the Appellee permitted unqualified and improperly trained staff to perform PET/CT scans, its claims for reimbursement from the government were fraudulent. The court states Relator's argument as follows:

> Medicare has mandated that diagnostic tests such as PET/CT scans involving the injection of nuclear material must be *in toto* performed by nuclear medicine technologists, and such tests performed by others are not considered reasonable and necessary. Because it is undisputed that [Appellee] permitted general radiographers to perform PET/CT scans after Mr. Ortolano had injected the radioactive isotopes, (and it is presumed for purposes of this motion that general radiographers were not qualified under Florida law), Relator concludes that the PET/CT scans were not "necessary," were unreimbursable as a matter

> of law, and [Appellee's] submission of such procedures for payment constituted direct fraud.

Id. at *11.

According to Medicare rules, a service must be "reasonable and necessary" to be reimbursable by the government. *See* 42 U.S.C. § 1395y(a)(1)(A) (2012); 42 C.F.R. § 411.15(k)(1) (2014). Congress mandated the Centers for Medicare and Medicaid Services ("CMS"), the agency authorized to operate the Medicare program, the responsibility to determine when an advancement, innovation, or improvement of an item or service provided to a Medicare patient is "reasonable and necessary." *See Hays v. Sebelius*, 589 F.3d 1279 (D.C. Cir. 2009) (noting that the Medicare Act grants the Secretary of Health & Human Services the ability to decide whether something is reasonable and necessary). Because CMS cannot practically evaluate every medical reimbursement claim, CMS has delegated the responsibility to make local coverage determinations ("LCDs") to Medicare Administrative Contractors ("MACs") to ensure that covered services are medically necessary. *See* 42 U.S.C. § 1395kk-l (2012) (containing the statutory authority for CMS to contract with MACs). CMS also has issued policy guidance in the form of Medicare Policy Manuals to guide MACs in the general processing of medical claims to ensure medical necessity. *See, e.g.*, Medicare *Benefit Policy Manual*, CTRS. FOR MEDICARE & MEDICAID SERVS., http://www.cms.gov/ Regulations-and-Guidance/Guidance/Manuals/ Internet-Only-Manuals-IOMs-

Items/CMS012673.html? DLPage=l&DLSort= 0&DLSortDir =ascending (last visited Jan. 30, 2013).

To be considered "reasonable and necessary" under Medicare rules, a service must be "safe and effective, not experimental or investigational, and appropriate." Medicare Benefit Policy Manual, Ch. 13. The term "appropriate" requires that the service is:

1. Furnished in accordance with accepted standards for medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member;
2. Furnished in a setting appropriate to the patient's medical need and condition;
3. Ordered and/or furnished by qualified personnel;
4. One that meets, but does not exceed, the patient's medical need; and
5. At least as beneficial as an existing and available medically appropriate alternative.

Id. at Section 5.1(C).

For the purposes of this appeal, the pertinent provision is the phrase "ordered and/or furnished by qualified personnel" as Appellant's FCA case is derived from the undisputed fact that Appellee failed to ensure his staff were in fact qualified.

It is inconceivable for CMS or its contractors to enunciate in regulations or guidance all circumstances in which a claim is properly paid or all qualifications that every health care entity must maintain in order to submit claims. The use of the term "qualified personnel" is meant to compel the providers to evaluate their eligibility under state law as well as any applicable federal regulations *before* submitting claims for reimbursement. Under Florida law, only a licensed nuclear medical technologist (or a licensed physician who is an authorized materials user on a radioactive materials license) can legally perform PET/CT scans. 5/6/14 Tr. 95:19-96:2; 103:9-25; 105:23-107:9. A nuclear medicine technologist is a graduate of an accredited two-year associates program and certified and licensed by the State of Florida after testing. *See, e.g.,* 5/5/14 Tr. 55:17-59:12; 5/6/14 Tr. 95:19-96:2.

The reasons for these protections are clear from the record-- a patient is radioactive after the radioisotope is injected, and there are dangers associated with all of the steps after the injection through the scan, including dangers to the patient and radioactive contamination to the technologist. 5/6/14 Tr. 35:16- 36:8; 76:3-77:19. At trial, Appellee admitted that the manufacturer of the scanner used such scanner because Florida law prohibits general radiographers from performing nuclear medicine procedures such as PET/CT scans. 5/7/14 Tr. 217:22-218:5. Appellee further admitted that supervision includes proper training. 5/7/14 Tr.

175:19-24. Nonetheless, Defendant permitted untrained and unqualified staff to perform procedures on patients and demanded payment from the government for overtly fraudulent claims.

Medicare has a recognized and statutory interest in ensuring "reasonable and necessary" care is provided by properly trained individuals. The district court's decision allows individuals who perform unlicensed and dangerous medical services to escape FCA liability. Appellee knowingly, and without concern for the dangers it created, submitted claims for reimbursement for services even though it knew it was dramatically out of compliance with the state licensure laws. Those laws protect patients and are key quality underpinnings of the Medicare and Medicaid system. Ignoring those requirements as not mandatory to Medicare reimbursement nullifies Medicare's requirement that services be reasonable and necessary, including being furnished by qualified personnel, to obtain reimbursement.

III. WHISTLEBLOWER LAWSUITS ARE CRUCIAL TO ACHIEVING HEALTH CARE TRANSPARENCY AND ENSURING PATIENTS RECEIVE QUALITY CARE.

Whistleblower lawsuits under the FCA, such as the present case, have proven to be the government's best weapon in uncovering fraud against the government and the delivery of poor care to patients. As such the jury's verdict, obtained after a full trial on the merits, should not have been ignored and the court

should not have entered a verdict for Appellee. The FCA is the single most effective tool in the fight against fraud perpetrated against the government. Between 2010 and 2014, the federal government recovered over $13 billion in healthcare fraud claims due to the FCA. *See* Dep't of Justice, *Fraud Statistics* 2, 4 (2014), http://goo.gl/zRbC3H.

Although the FCA provides the federal government with broad powers to combat healthcare fraud, public enforcement of the statute can be limited. Resource constraints, such as budgetary restrictions, often prevent the U.S. Department of Justice ("DOJ") and other law enforcement from investigating potential instances of healthcare fraud. *See* David Freeman Angstrom, *Private Enforcement's Pathways: Lessons from Qui Tam Litigation*, 114 Colum. L. Rev. 1913, 1986-87 (2014). Similarly, the high degree of automation in the federal government's processing of healthcare reimbursement claims makes discovering healthcare fraud particularly difficult for government regulators. Malcolm K. Sparrow, *License to Steal: How Fraud Bleeds America's Health Care System* 29-30 (2000) (discussing the ease with which healthcare fraud can be perpetrated as a result of Medicare's automated billing scheme).

In the midst of these constraints, whistleblowers or "relators" step in and play a key role in the success of the FCA. Relators largely succeed where public enforcement lags. Relators are uniquely situated to uncover health care fraud that

may be hidden from healthcare reimbursement claims processors and law enforcement because they normally work in and among defrauding parties, and thus can uncover and expose fraud that might not otherwise be found. *See* S. Rep. No. 99-345, at 3 (1986) ("Detecting fraud is usually very difficult without the cooperation of individuals who are either close observers or otherwise involved in the fraudulent activity."); Peter D. Banick, Note, *The "In-house" Whistleblower: Walking the Line Between "Good Cop, Bad Cop,"* 37 Wm. Mitchell L. Rev. 1868, 1875 (2011) (whistleblowers are "often in a particularly unique position—e.g., gatekeeper, business executive, compliance facilitator—that increases the likelihood of discovery and the need to report wrongdoing"). By their very definition, relators will have an "*independent* … and material" knowledge of the fraud being perpetrated, and thus serve an important role in bringing suspected fraud to light. 31 U.S.C. § 3730(e)(4)(B) (2012) (emphasis added).

The importance of relators in enforcing the FCA and, thus, combating healthcare fraud is underscored by the amount of money their claims recoup for the federal government and the oversight they provide for vulnerable populations. Financially, relators have helped the federal government recover billions of dollars. For example, between 2010 and 2014, relator-led FCA actions alleging healthcare fraud contributed over $11 billion to federal revenue, an amount that is eighty-seven percent of all healthcare funds recouped by the federal government during

this period. *See* Dep't of Justice, *Fraud Statistics* 4 (2014), http://goo.gl/zRbC3H. Similarly, the largest healthcare fraud settlements from the past three years originated in FCA complaints filed by relators. *See* Press Release, U.S. Dep't of Justice, DaVita to Pay $350 Million to Resolve Allegations of Illegal Kickbacks (Oct. 22, 2014), http://goo.gl/SJ3eix (largest settlement for 2014); Press Release, U.S. Dep't of Justice, Johnson & Johnson to Pay More Than $2.2 Billion to Resolve Criminal and Civil Investigations (Nov. 4, 2013), http://goo.gl/YUczN0 (largest settlement for 2013); Press Release, U.S. Dep't of Justice, GlaxoSmithKline to Plead Guilty and Pay $3 Billion to Resolve Fraud Allegations and Failure to Report Safety Data (July 2, 2012), http://goo.gl/OOtLZZ (largest settlement for 2012). In recognition of the importance of relators in assisting the federal government in recovering defrauded funds, the DOJ has commented that relators are "essential to guarding the treasury and deterring others from exploiting and misusing taxpayer dollars." Press Release, U.S. Dep't of Justice, Justice Department Recovers Nearly $6 Billion from False Claims Act Cases in Fiscal Year 2014 (Nov. 20, 2014), http://goo.gl/XZ478M.

Relators' role in enforcing the FCA also helps protect vulnerable populations by exposing fraudulent and substandard healthcare. The relators' ability to expose poor care provided to older people is illustrated by a review of recent FCA settlements. For example, in St. Louis, Missouri, relators who were

former employees of the Cathedral Rock Corporation alerted the DOJ to extreme health and safety violations at the company's nursing facilities:

> [N]umerous residents suffered from malnutrition, dehydration, preventable pressure sores and preventable side effects from not receiving their medications. Some residents simply wandered away from the homes, sometimes with the Cathedral Rock staff not noticing that the residents were gone until many hours later. One resident was almost hit by a car after leaving a Cathedral Rock facility while using a walker. Other residents underwent amputations of feet and legs because pressure sores formed and were left untreated, and in some cases the pressure sores had become infested with maggots.

Press Release, Fed. Bureau of Investigation, Cathedral Rock Nursing Homes and a Nursing Home Operator Resolve Criminal and Civil HealthCare Fraud Allegations Related to Failure of Care and Agree to Pay the United States Over $1.6 Million (Jan. 7, 2010), https://goo.gl/kngj3I. The defendant, C. Kent Harrington and his company, settled with the federal government for over $1.6 million, but, the most important outcome of the case concerned the health and safety of the residents of the nursing facilities. *Id.*

Another example occurred in March 2015, when Adventist Health System Sunbelt Healthcare Corporation agreed to pay $5,412,502 to settle relator-led FCA allegations that it provided radiation services to cancer patients that were not supervised by a radiation oncologist or other qualified person. Press Release, U.S. Dep't of Justice, Adventist Health System to Pay $5.4 Million to Resolve False Claims Act Allegations (March 19, 2015), http://goo.gl/6sJ8Pl.

Accordingly, relators play an integral role in enforcing the FCA and protecting patients. Their unique position within defrauding entities allows them to broadly expose and prosecute fraud. Relators' FCA actions have helped recoup billions of dollars to the federal government, and advanced public health and safety, especially among vulnerable populations. Here, in finding for Appellant, this Court would preserve the ability of relators to expose healthcare fraud, and help ensure the continued protection of the federal government's coffers and vulnerable populations.

CONCLUSION

For the foregoing reasons, Amici AARP and Center for Medicare Advocacy, Inc. respectfully submit that the decision of the U.S. District Court for the Middle District of Florida be reversed and the judgment reflecting the jury's verdict should be entered.

July 8, 2015

Respectfully submitted,

/s/ Maame Gyamfi
Maame Gyamfi

On the Brief
Kelly Bagby
William Thanhauser
AARP Foundation Litigation
601 E Street, NW
Washington, D.C. 20049
Phone: (202) 434-6291

Counsel for Amici

CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limitation of Fed. R. App. P. 32(a)(7)(B) because this brief contains 5,612 words, excluding the parts of the brief exempted by Fed. R. Ap. P. 32(a)(7)(B)(iii).

This brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type style requirements of Fed. R. App. P. 32(a)(6) because this brief has been prepared in a proportionally spaced typeface using Microsoft Word 2010 in Times New Roman 14-point font.

July 8, 2015 *<u>/s/ Maame Gyamfi</u>*
Maame Gyamfi

CERTIFICATE OF SERVICE

I hereby certify that on July 8, 2015, I electronically filed the original of the foregoing document with the clerk of this Court by using the CM/ECF system. I certify that the participants in the case are registered CM/ECF users and that service will be accomplished by the appellate CM/ECF system.

Date: July 8, 2015 *<u>/s/ Maame Gyamfi</u>*
Maame Gyamfi