

# 05-2951-cv

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IN THE UNITED STATES COURT OF APPEALS  
FOR THE SECOND CIRCUIT

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**IN RE: CARDIAC DEVICES QUI TAM LITIGATION**

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**ON APPEAL FROM THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF CONNECTICUT**

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Brief for Amici Curiae, Association of American Medical Colleges &  
American Hospital Association in Support of Appellants/Reversal

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## **RULE 29 STATEMENT**

Counsel for Amici certifies pursuant to Fed. R. App. P. 29(a) that all parties have consented to the filing of this brief.

## **INTEREST OF THE AMICI**

The Association of American Medical Colleges (“AAMC”) represents the nation’s 126 accredited medical schools, nearly 400 major teaching hospitals and health systems, and over 105,000 faculty in 98 academic and scientific societies. AAMC’s mission is to improve public health by enhancing the effectiveness of academic medicine. It supports its members in their performance of education, research, development, and providing patient care in academic settings. The American Hospital Association (“AHA”) represents 4,800 hospitals, health systems and other health care organizations, and 33,000 individual members. AHA is the national advocate for its members on health care issues. It ensures that its members’ perspectives are considered in the development of national health care policy in Congress and the courts, and, of note here, has instituted a process with the Centers for Medicare & Medicaid Services of the U.S. Department of Health and Human Services (“CMS”) to obtain guidance on complex regulatory interpretation issues.

Amici share strong commitments to ensuring that hospitals have the information and tools necessary to comply with the vast array of federal and state laws and regulations governing reimbursement and regularly provide updates to their members on CMS guidance. The questions presented in this appeal have tremendous significance to Amici’s members, many of whom may be subjected to

litigation initiated by private citizens and prosecuted by the Department of Justice (“DOJ”) under the False Claims Act (“FCA”).

## **FACTUAL AND LEGAL BACKGROUND**

### **A. Flip-Flopping Federal Reimbursement Policies**

#### **1. Policies Prior to 1986**

Prior to the adoption of the 1986 Manual provision at issue (“Manual” or “1986 Manual”), coverage determinations for cardiac surgeries generally were left to the local Medicare fiscal intermediaries responsible for day-to-day administration of the Medicare Part A program. Hospitals routinely billed Medicare for inpatient admissions in which patients’ treatments included cardiac devices available for use in hospitals under Investigational Device Exemptions (“IDES”) but not yet approved by the Food and Drug Administration (“FDA”) for general marketing. Such services were regarded as medically “reasonable and necessary,” provided the investigational medical devices (“IMDs”) were “accepted by the professional medical community as an effective and proven treatment,” or there was “authoritative evidence” the treatment or device was safe and effective.<sup>1</sup>

#### **2. 1986 Manual Reversing the Prevailing Policy**

In 1986, CMS precipitously reversed prevailing coverage policy by issuing the 1986 Manual<sup>2</sup> (JA 1020) It relevantly provides:

Medical devices which have not been approved for marketing by the FDA are considered investigational by

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<sup>1</sup> Part A Intermediary Letter (“IL”) No. 77-4 (Jan. 1977) (Joint Appendix [hereafter “JA”] at 1020).

<sup>2</sup> Hospital Manual § 260.1 (and identical provisions at Intermediary Manual § 3151.1 and Medicare Carriers Manual § 2301.1). Appellants’ Special App. at 3-4.

Medicare and are not considered reasonable and necessary for the diagnosis and treatment of illness or injury, or to improve the functioning of a malformed body member. Program payment, therefore, may not be made for medical procedures or services using [such] devices ... (emphasis added).

Described by CMS as “new policy” (Supplemental App. [SA] at 59), the Manual withdrew Medicare coverage of all hospital services involving IMDs performed as of July 25, 1986. This presumptive denial ignored whether the overall procedure was medically necessary, or whether the IMD was merely incidental to the overall procedure. This “fundamental shift” in coverage<sup>3</sup> occurred without the benefit of notice and comment rulemaking, or publication of an “interpretative rule” in the Federal Register.<sup>4</sup> As the courts in Yale-New Haven and Cedars-Sinai Med. Ctr. v. Shalala, 939 F. Supp. 1457 (C.D. Cal. 1996), *vacated on other grounds*, 125 F.3d 765 (9th Cir. 1997) observed, the new policy lacked any substantial evidentiary basis because it was issued without reasoned analysis or reference to data justifying a reversal of the interpretation which had prevailed since 1977.

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<sup>3</sup> Ruling on Motions for Summary Judgment, Yale – New Haven Hosp., Inc. v. Shalala, No: 3:99cv 2546 (PCD) (hereinafter “Yale-New Haven”) slip. op. at 16.

<sup>4</sup> While it excuses interpretive rules from the 30-day advance notice requirement, the APA still requires publication in the Federal Register and codification in the Code of Federal Regulations. See 5 U.S.C. §§ 552(a)(1)(D) Hartnett v. Cleland, 434 F. Supp. 18, 22 n.7 (D.S.C. 1977) (and cases cited therein) (statements of policy not duly published in Federal Register do not create a binding norm); Lewis-Mota v. Sec’y of Labor, 469 F.2d 478 (2d Cir. 1972). Beginning in 1988, CMS’s predecessor, HCFA, began to publish issuances of new manual provisions on a quarterly basis. See 42 U.S.C. § 1395hh(c); 53 Fed. Reg. 21730 (June 9, 1988). The 1986 Manual predated that practice.

### 3. 1995 Rule Overturning the 1986 Manual

In 1995, CMS reversed the position espoused in the 1986 Manual following notice and comment rulemaking,<sup>5</sup> and effectively re-implemented its original “reasonable and necessary” standard for IMDs. Specifically, CMS divided the most sophisticated IMDs into categories “A” and “B,” and permitted Medicare reimbursement for inpatient treatments including those in Category B, which includes “virtually all of the” cardiac devices that are the subject of this litigation.<sup>6</sup> In essentially reverting to its original policy, CMS explained that it “intended to provide Medicare beneficiaries with greater access to advances in medical technology and to encourage clinical researchers to conduct high quality studies of newer technologies.” 60 Fed. Reg. at 48418. In addition to this “beneficial effect,” CMS observed that the new rule would not adversely financially affect Medicare since the program always pays the same amount per admission, regardless of the device used. *Id.* at 48422.

#### **B. Claims Brought Against the Hospitals**

In the midst of CMS’s policy changes on treatments involving IMDs, a sales representative for a cardiac device company filed a sealed *qui tam* action against 132 clinical trial hospitals in thirty (30) states. In re Cardiac Devices, Qui Tam Litig., 221 F.R.D. 318, 322 (D. Conn. 2004). Defendants included the most

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<sup>5</sup> 60 Fed. Reg. 48417, 48422 (Sept. 19, 1995), adding 42 C.F.R. §§ 405.201—405.215.

<sup>6</sup> Denominated as “non-experimental” and covered as “reasonable and necessary,” 60 Fed. Reg. at 48419, 48423, Category B devices include: (i) second manufacturers’ “substantially equivalent” versions of a device already approved for general marketing by a prior manufacturer; and (ii) devices representing a “refinement” to an approved device for which the “underlying questions of safety and effectiveness of that device type have been resolved.” 42 C.F.R. § 405.201.

accomplished academic medical treatment and research centers in the United States. The complaint alleged the hospitals all defrauded Medicare by billing for inpatient services that included IMDs. *Id.* at 323-24. Despite CMS's intervening policy change announcing that the use of these same devices was again considered reasonable and necessary, DOJ assumed the prosecution of FCA claims against hospitals whose billing practices between 1986 and 1995 violated the Manual. The government's prosecution has now dragged on for well over a decade.

### **INTRODUCTION AND SUMMARY**

Defendants in this litigation are a large group of teaching hospitals that serve their communities daily by providing the most advanced treatments available to their patients, including Medicare beneficiaries. For Medicare patients who needed cardiac surgery, the hospitals provided the most current, life-saving technologies. DOJ seeks penalties and treble damages under the FCA from these caregivers for billing Medicare consistent with historic norms and prevailing standards of care because the services did not conform to a suspect informal guideline that two courts have since declared invalid. This Court should soundly reject these claims.

The guideline in question is a 1986 Manual provision that was never vetted through notice and comment, or even promulgated as an interpretative regulation. Sustaining these FCA claims would enable DOJ to transform a non-binding administrative pronouncement into a nuclear weapon for extracting hundreds of millions of dollars in settlements or fines from hospitals across the country. These claims are even more anomalous considering that CMS reversed the interim 1986 Manual interpretation when it finally addressed these same issues in 1995 through

formal rulemaking. As a necessary element of its case, DOJ thus accuses hospitals of “falsely” claiming that the use of cardiac devices was medically “reasonable and necessary” *after* CMS’s final regulation repudiated the informal guideline on which the FCA claims are based, declared the use of these same devices reasonable and necessary, and *validated* the propriety of the hospitals’ claims.

The government’s position is particularly troubling because DOJ is aggressively brandishing the FCA to dictate the “medical necessity” of particular procedures for cardiac patients. In the Medicare statute (the “Act”), Congress expressly disavowed the intention to control how medicine is practiced, and mandated that Medicare patients be treated like all other hospital patients receiving inpatient care. The Manual purported to override the rights of Medicare patients to receive the treatments deemed appropriate by their treating physicians. CMS should not be permitted to presumptively dictate to physicians and hospitals what procedures and treatments are medically appropriate absent compliance with notice and comment rulemaking requirements. Placing caregivers at risk of FCA prosecution for what amounts to providing Medicare recipients optimal care would dangerously cede control over the delivery of care to the government. And DOJ should not be permitted to use the FCA to second-guess CMS’s own more recent decision that these devices *are* medically reasonable and necessary.

DOJ’s resort to the FCA also should be rejected because the alleged violations of the 1986 Manual caused the United States no financial injury. Under the DRG System, Medicare pays hospitals a single fixed fee per inpatient case based on the discharge diagnosis. Hospitals were paid the same amount whether they used a more expensive cutting edge device, or an older less expensive one, so

the use of the devices targeted by the 1986 Manual caused no financial injury to Medicare. This Circuit has not yet held that the United States may sue under the FCA without sustaining any monetary damages, and should decline to do so here.

The lower court's decision inappropriately rewards the government for contravening the Act by allowing an informal guidance to dictate medical treatment policies. Its decision was grounded in an erroneous understanding of the Medicare system and the providers' "certifications." Under the DRG system, program rules required hospitals to include on their bills to Medicare a defined list of information, including the patients' diagnoses and the procedures they have undergone. Hospitals, however, were *not required* to specify or certify, and therefore could not mislead or affirmatively falsify a claim relating to, the type of cardiac device used. The district court purported to find an express false certification claim based on hospitals' certifications that they prepared their annual cost reports in accordance with applicable instructions. This approach misperceives the cost-reporting instructions, and inappropriately presumes that verifications on cost reports relate back months or years to claims made following each patient's discharge. DOJ's theories of FCA liability stretch the concept of false certification beyond any reasonable boundaries, and should be rejected by this Court.

## ARGUMENT

### **I. THIS COURT SHOULD NOT RECOGNIZE A FCA CLAIM BASED ON THE FAILURE TO COMPLY WITH A NON-BINDING AGENCY GUIDELINE**

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#### **A. The Government Should Not Be Rewarded For Circumventing the Administrative Procedure Act By Being Permitted to Pursue Potent FCA Prosecutions**

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The United States should not be permitted to leverage the enforcement of a facially suspect manual provision, especially one that was ultimately declared invalid by two different courts and repudiated by the agency that issued it, into a nationwide FCA prosecution.

To temper the powers of unelected officials, including the Secretary of HHS and the Administrator of CMS, the Administrative Procedure Act (“APA”) and the Social Security Act (42 U.S.C. § 1395hh) prescribe generally that agencies may establish binding obligations and norms only through notice and comment rulemaking. Even where an agency issues an “interpretive” regulation and is permitted to bypass public notice and comment, the APA still requires formal publication in advance of the rule’s effective date. 5 U.S.C. § 552(a)(1)(D). Publication ensures widespread pronouncement of new policy and is likely to garner congressional awareness.<sup>7</sup> Further, interpretive “regulations” must be vetted at the highest level of the agency, and approved by the Office of Management and Budget (“OMB”).<sup>8</sup>

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<sup>7</sup> Congress is presumed aware of published regulations. See Haig v. Agee, 453 U.S. 280, 300 (1981).

<sup>8</sup> OMB review of agency rules is required prior to their publication under Exec. Order 12291, 46 Fed. Reg. 13193 (June 13, 1986), which applies to both



It is now a truism that a manual provision that has neither been published in the Federal Register nor codified in the CFR is not “binding,” lacks “the force or effect of law,” and merely affords guidance as to how the agency intends to apply the law (for example, in a future adjudication).<sup>9</sup> Further, unlike positions published regulations, interested parties have no right under the APA to petition HHS to review CMS’s manuals. See 5 U.S.C. § 553(e). Significantly, in deciding Medicare Part A appeals pursuant to 42 U.S.C. §1395oo(a), the Provider Reimbursement Review Board (“PRRB”) must apply published agency rules, but is *not bound by and may choose to disagree with or reject* provisions of the CMS manuals.<sup>10</sup>

Although Chevron U.S.A., Inc. v. Natural Res. Def. Council, Inc., 467 U.S. 837 (1984) established that even “interpretive rules” may be entitled to substantial

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interpretive and legislative “regulations.” When OMB reviews “all rules other than major rules,” notices of proposed rulemaking and final rules must be submitted in advance to the Director, who considers, *inter alia*, beneficial and adverse effects, including those that “cannot be quantified in monetary terms.” 46 Fed. Reg. at 13194. Accord Exec. Order No. 12866, 3 C.F.R. § 638 (1994), *reprinted in* 5 U.S.C. § 601 (2000).

<sup>9</sup> See, e.g., St. Mary’s Hosp. of Troy v. Blue Cross Blue Shield Ass’n, 788 F.2d 288 (2d Cir. 1986); Phoenix Baptist Hosp. & Med. Ctr. v. Heckler, 767 F.2d 1304, 1307 (9th Cir. 1985) (“The Manual is a guide for intermediaries in applying the Medicare statute and reimbursement regulations and does not have the binding effect of law or regulation.”); New York City Employees’ Ret. Sys. v. SEC, 45 F.3d 7, 12 (2d Cir. 1995) (informal letter ruling is an “interpretation” [that] binds no one”).

<sup>10</sup> See 42 U.S.C. § 1395oo(f)(1); 42 C.F.R. § 405.1867 (PRRB is bound by regulations, not manuals); PRRB Instructions, Part I (same); see, e.g., Sunbelt Health Care Ctrs. Group Appeal, PRRB Dec. No. 97-D13 (Dec. 3, 1996), *reprinted in* Medicare & Medicaid Guide (CCH) ¶ 44,923, St. Mary’s Hosp. & Med. Ctr. San Francisco, CA, PRRB Dec. No. 90-D34 (Jan. 18, 1990), *reprinted in* Medicare & Medicaid Guide (CCH) ¶ 38,627 (PRRB is free to reject manual provisions Board views as inconsistent with statute or regulations).

judicial deference, subsequent Supreme Court decisions have sharply limited the deference accorded less formal agency interpretations, such as manual provisions, that are approved at lower levels of an agency under less exacting standards.<sup>11</sup> “To grant Chevron deference to informal agency interpretation would unduly validate the results of an informal process.” Madison v. Res. For Human Dev., Inc., 233 F.3d 175, 186 (3d Cir. 2000).

Here, the 1986 Manual – which has since been declared invalid in both Yale-New Haven and Cedars Sinai – was facially suspect. An informal manual provision is a dubious vehicle for setting *per se* coverage rules for complex medical procedures. This particular provision – which limits services available to beneficiaries and reimbursements to providers – embodies a substantive pronouncement that should never have been adopted without the benefit of full notice and comment rulemaking.<sup>12</sup> Further, the 1986 Manual reversed the

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<sup>11</sup> United States v. Mead Corp., 533 U.S. 218, 234 (2001) (customs letter ruling, like a “manual,” enforcement guidelines or other informal interpretations, is not entitled to Chevron deference); Christensen v. Harris County, 529 U.S. 576, 587 (2000) (same).

<sup>12</sup> Agency pronouncements that modify existing rights and obligations are deemed “legislative, and thus are subject to notice and comment rulemaking. See Sweet v. Sheahan, 235 F.3d 80, 90 (2d Cir. 2000) Nat’l Med. Enters. v. Shalala, 826 F. Supp. 558 (D.D.C. 1993). Congress has recognized the importance of CMS’s using transparent notice and comment procedure in rendering national coverage determinations (“NCDs”), which was not done here. The APA was made applicable to Medicare regulations in 1971. See Bedford County Gen. Hosp. v. Heckler, 757 F.2d 87, 90 (6th Cir. 1985). The Act was amended in 1987 – after CMS acted here via a Manual – to establish a process for publishing NCDs regarding the medical necessity of specific services subject to judicial review. See 42 U.S.C. §§ 1395hh(a)(2)&(c), 1395ff(b)(3); 54 Fed. Reg. 34555 (Aug. 21, 1989). The Medicare Modernization Act of 2003 (“MMA”), Pub. L. No. 108-173, required CMS to make a draft of a proposed coverage decision available on its

agency's prior interpretation of the application of the "reasonable and necessary" standard to cardiac devices without any supporting justification or reasoned analysis.<sup>13</sup> Under the law of several circuits, agency pronouncements that might otherwise be labeled as interpretive are treated as substantive rules, subject to notice and comment requirements, where they change, rather than merely clarify, the agency's own pre-existing interpretation of law.<sup>14</sup> This position is followed in D.C. – the Secretary's "home circuit" in which *all provider appeals may be filed* under 42 U.S.C. § 1395oo(f)(1).

Because the 1986 Manual represented an informal, wholesale reversal of the agency's prior interpretation of the "reasonable and necessary" standard that is neither legally binding nor entitled to Chevron deference, it should be viewed as *presumptively invalid*, not, as the government argues, presumptively binding. The government's contention that hospitals should be subject to FCA prosecutions for trying to "cheat the government" even if the Manual is later "found to be invalid" (In re Cardiac Devices, 221 F.R.D. at 343) is similarly unpersuasive. It rests directly on the unfounded assumption that the Manual is legally "binding." Id.

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website for public review and comment. Thus, the legislative process began and ended by requiring notice and comment and industry input for all proposed NCDs.

<sup>13</sup> While agency interpretations are not "set in stone," an agency acts arbitrarily and capriciously when it reverses a prior position or interpretation without at least providing a reasoned explanation capable of supporting the reversal of field.

Smiley v. Citibank, 517 U.S. 735, 742 (1996); Thomas Jefferson Univ. Hosp. v. Shalala, 512 U.S. 504, 512 (1994); Motor Veh. Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 46-57 (1983). There is a heightened obligation on an agency to justify a clear departure from prior agency norms. Verizon Commc'ns, Inc. v. FCC, 535 U.S. 467, 503 (2002).

<sup>14</sup> See, e.g., Shell Offshore v. Babbitt, 283 F.3d 662 (5th Cir. 2001); Paralyzed Veterans of Am. v. D.C. Arena, L.P., 117 F.3d 579 (D.C. Cir. 1997); Mt. Diablo Hosp. v. Bowen, 860 F.2d 951 (9th Cir. 1988).

Because it properly may be invoked only as a form of informal guidance, it is incongruous that a provider that fails to hew to the Manual should be subject to prosecution under the FCA. Permitting these claims to proceed would inappropriately reward the government for evading statutory rulemaking obligations.

**B. The Manual Dictated Standards of Medical Care and Thus Further Counsels Against Recognition of FCA Claims**

The government’s manipulation of the informal 1986 Manual into a potent FCA weapon is particularly disturbing given that it dictates the medical necessity of complex cardiac treatments. While Medicare coverage is limited by statute to services that are “medically reasonable and necessary,” 42 U.S.C. § 1395y(a)(1), Congress excluded very few items or services from coverage,<sup>15</sup> and plainly expected the Secretary to tread lightly in this area.

In response to concerns about “federalizing” the practice of medicine through the creation of the Medicare program, Congress underscored in the Act’s preamble that the Secretary was not “authorize[d]” to “exercise any supervision or control over . . . the manner in which medical services are provided.” 42 U.S.C. § 1395 (emphasis added). The Senate Report explained (emphasis added):

The bill specifically prohibits the Federal Government from exercising supervision or control over the practice of medicine, [or] the manner in which medical services are provided. . . . The responsibility for, and the control of care of the beneficiaries rests with the hospitals, . . . [and] the beneficiaries’ physicians, etc.

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<sup>15</sup> These include, *inter alia*, custodial care, comfort items, shoe inserts, routine foot care and cosmetic surgery. 42 U.S.C. § 1395y(a)(6)-(22). None of these remotely resembles IMDs.

The . . . physician is to be the key figure in determining utilization of health services – and . . . it is the physician who is to decide upon admission to a hospital, order tests, drugs and treatments . . .

S. Rep. No. 404, 89<sup>th</sup> Cong., 1<sup>st</sup> Sess. (June 30, 1965), accompanying H.R. 6675, reprinted in U.S.C.C.A.N. 1943, 1965, 1986. Similarly, Congress did not intend to create separate systems of medical delivery for Medicare and non-Medicare inpatients; the Act states expressly that Medicare patients shall receive the *same* “supplies, appliances and equipment as are ordinarily furnished by the hospital for care and treatment of inpatients.” 42 U.S.C. § 1395x(b).

These statutory commands evince a strong congressional policy against micromanaging hospital care under the guise of administering Medicare reimbursement. Because the use of an IMD does not financially affect Medicare (*infra*, at II), the Manual can only be viewed as an attempt to dictate the practice of medicine. By removing Medicare coverage for the same devices routinely used by hospitals and physicians to treat non-Medicare patients, the Manual conflicted squarely with both § 1395 and § 1395x(b). It is therefore due no deference and must be rejected under the first prong of the Chevron analysis. See Mercy Catholic Med. Ctr. v. Thompson, 380 F.3d 142, 155-156 (3d Cir. 2004).

At the very least, if CMS seeks independently to dictate standards of medical care that are subject to FCA “enforcement,” it should do so only through notice and comment proceedings pursuant to 5 U.S.C. § 553(b) & (c) and the MMA (note 12, *supra*), where the views of the medical community are placed on the record, and all material concerns and issues are addressed. The 1995 final rule with comment, which was informed by input from the FDA and the healthcare community, underscores the importance of this process and the degree to which the

1986 Manual interfered with the delivery of medical care to the detriment of Medicare patients. CMS there acknowledged that by withdrawing the “presumed exclusion” of coverage under the Manual, “Medicare beneficiaries” would be afforded “greater access to advances in medical technology.” 60 Fed. Reg. at 48418, 48422. Accord id. at 48419 (the 1995 rule “is expected to benefit Medicare beneficiaries”).<sup>16</sup> These statements amount to an acknowledgement that the 1986 Manual *deprived* Medicare recipients of access to advanced medical technologies available to other patients.

## **II. THIS COURT SHOULD REJECT THE GOVERNMENT’S FCA CLAIMS BECAUSE THE ALLEGED UNDERLYING VIOLATION OF THE MANUAL CAUSED NO FINANCIAL HARM TO THE GOVERNMENT**

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The government’s reliance on the FCA also should be rejected because hospitals did not and could not cause the United States financial harm by using the IMDs in question.

The circuits are split as to whether monetary damages to the United States is required by the FCA. Many courts, including the Federal Circuit, and the Southern District of New York, have concluded that monetary damages is an element of a FCA claim.<sup>17</sup> The Third Circuit concluded that “[w]hile recovery ... is not

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<sup>16</sup> The benefits of using cutting edge IMDs have been catalogued in peer reviewed journals See, e.g., S. Nisam, *Annals of Noninvasive Electrocardiology*, Vol. 2 No. 1 (Jan. 1997); J. Porterfield and L. Porterfield, *Primary Cardiology*, Vol. 21 No. 11 (Nov. 1995). (Yale-New Haven JA at 125-140.)

<sup>17</sup> See Young-Monteway, Inc. v. United States, 15 F.3d 1040, 1043 (Fed. Cir. 1994); United States ex rel. Mikes v. Straus, 84 F. Supp. 2d 427, 440 (S.D.N.Y. 1999); Blusal Meats, Inc. v. United States, 638 F. Supp. 824 (S.D.N.Y. 1986), *aff’d*, 817 F.2d 1007 (2d Cir. 1987). But see Harrison v. Westinghouse Savannah River Co., 176 F.3d 776, 785 (4<sup>th</sup> Cir. 1999).

dependant on the government’s sustaining monetary damages, the Act is only intended to cover instances of fraud that might result in financial loss to the government.” Hitchins v. Wilentz, Goldman & Spitzer, 253 F.3d 176, 183 (3d Cir. 2001). See also Mikes v. Straus, 274 F.3d, 687, 697 (2d Cir. 2001), *citing United States v. Hess*, 317 U.S. 537, 549 (1943) (“the Act’s primary purpose is to indemnify the government – through its restitutionary penalty provisions – against losses caused by a defendant’s fraud”). This Court reserved decision on this issue in Mikes after concluding that FCA prosecutions for quality of care violations was impermissible on other grounds. Amici urge the Court to reject the government’s claims on this basis here.

A “violation” of the 1986 Manual could not financially harm the United States because these cases all arose under the DRG system, under which each hospital is paid a uniform, fixed overall fee per discharge. Whether a hospital used “Manufacturer A’s” marketable first generation pacemaker rather than “Manufacturer B’s” substantially equivalent version, or “Manufacturer C’s” improved version, the Medicare DRG payment for the admission would not change by a penny. Cf. United States ex rel. Schell v. Battle Creek Health Sys., 419 F.3d 535 (6th Cir. 2005) (summary judgment on FCA claims turns on whether, under the facts and the applicable reimbursement system, the claims presented actually increased Medicare expenditures). This point is undisputed and was conceded in the preamble to the 1995 rule as a matter of law. See 60 Fed. Reg. at 48422 (“Hospitals are paid [a flat fee] on a prospective basis” under the DRG system “so that prices are not adjusted based on changes in the price-component (that is, device cost) of individual DRGs”); 48421 (“Payment ... under the 1995 final rule .

. . . may not exceed the amount that would have been paid for a currently used device serving the same medical purpose . . . In cases involving a hospital stay, the diagnosis related group (DRG) payment under the prospective payment system ordinarily will not be affected.”).

Ironically, the later generation IMDs whose use was conclusorily and improvidently labeled medically unnecessary by the 1986 Manual represented refinements, improvements and “advances” over the versions previously approved for general marketing. If a newer device that the treating physician deemed better and more appropriate cost more than the version approved for general marketing, the hospital still received the same DRG payment, and made less money than if it had provided the beneficiary with the older technology. Thus, Medicare actually “got more for its money” from hospitals that continued to provide these cutting edge IMDs to Medicare beneficiaries. This point dramatically underscores the absurdity of treating nonconformance with the 1986 Manual provision as a FCA violation.

### **III. THERE WAS NO FALSE CERTIFICATION OR VALID BASIS TO “IMPLY” A FALSE CERTIFICATION CAPABLE OF SUSTAINING FCA CLAIMS**

The district court incorrectly endorsed the government’s claims that: (i) hospitals expressly “falsely certified” in their annual cost reports that the devices in question were covered under the 1986 Manual; and (ii) “impliedly falsely certified” that the devices were medically reasonable and necessary in billing for them.



**A. The Government Fails to Assert a Valid Express False Certification Claim**

The government contends that in billing in derogation of the 1986 Manual, hospitals falsely certified information on their UB-82s, and falsely certified that each of their annual Medicare cost reports “were true, correct, and accurate and prepared in accordance with applicable instructions.” In re Cardiac Devices, 221 F.R.D. at 343. Neither theory is convincing.

The short answer is that the reimbursement claims all were based on accurate, truthful information and certifications. The claims at issue were processed under a prospective payment system (“PPS”), under which hospitals are paid daily or weekly for inpatient cases for each discharge on a claim-by-claim basis. See 42 U.S.C. § 1395ww(d); Washington Hosp. Ctr. v. Bowen, 795 F.2d 139, 145 (D.C. Cir. 1986). These individual inpatient cases were not paid at year end through the cost report. To bill for such claims, hospitals submitted a Uniform Billing Form (or “UB-82,” or “HCFA 1450”).<sup>18</sup> This form requests a variety of information, including a list of the patient’s primary and secondary diagnoses (by CPT code), the procedures rendered during the hospital stay, and the hospital’s usual charges for the services. The provider “certifies” that this information and certain other specifically incorporated assurances are true and correct. *Nowhere* does the form require a listing of specific devices or a certification that only devices approved for general marketing were used.

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<sup>18</sup> JA 987-989. In 1994, the program switched to the UB-92 form, which contained a column (field 48) for listing “non-covered charges.” (JA 990) There was no similar column on the UB-82 used throughout most of the periods covered by the FCA claims.

DOJ thus cannot viably allege that any defendant expressly falsely certified compliance with the 1986 Manual on the UB-82. Instead, DOJ contends that hospitals should have disclosed in the general “Remarks” section of the UB-82 (and, later, the UB-92) that the claims did not comply with the 1986 Manual, characterizing these non-disclosures as “claims that disguise non-covered services as covered.” 221 F.R.D. at 343. DOJ’s theory rests on the failure to affirmatively disclose information not required by the government’s own forms, and would create FCA liability based only on a duty to supply information that the comprehensive UB-82 does not require. However, there “can only be liability under the [FCA] where the defendant has an obligation to disclose omitted information.” United States ex rel. Berge v. Bd. of Trs. of Univ. of Ala., 104 F.3d 1453, 1461 (4th Cir.), *cert. denied*, 522 U.S. 916 (1997).

The district court understandably did not bite on this theory, but instead relied on the hospitals’ certifications that their annual cost reports were “true, correct, and complete” and “prepared in accordance with applicable instructions, except as noted.” Id. at 345-347. In effect, the district court found a false certification that the “applicable instructions” for cost reports were followed, based on the view that hospitals’ earlier submissions of UB-82s did not conform to the Manual. It reasoned that “[t]o hold otherwise would give defendants free reign to submit claims for any and all types of non-covered services.” Id. at 347. These conclusions do not fly.

As the district court recognized, the “claims” at issue were submissions of UB-82s; the subsequent cost reports were not “requests for payments with respect to [these] specific services provided to Medicare beneficiaries.” 221 F.R.D. at 343-344. Under PPS, cost reports are not the means through which individual inpatient discharges are paid or adjusted. Rather, they are used to allocate overall hospital costs, reconcile certain interim payments, establish cost-to-charge ratios, and retrospectively allocate costs for “outpatient services.” *Id.* at 344 & n.42. See also 60 Fed. Reg. 48422 (distinguishing between DRG reimbursements and cost-based reimbursements that prevailed for “outpatient” services). Certifications that *cost reporting instructions* have been followed have nothing to do with the “claims” represented by the submission of UB-82’s, and there is no allegation that hospitals did not follow the instructions actually “applicable” to the preparation of the *cost reports*. DOJ’s creative effort to twist the cost reporting signature into a false certification of reimbursement claims on UB-82s simply is unfounded.<sup>19</sup>

Furthermore, in relying on the annual cost report, the government posits a “false certification” that allegedly occurred long after the requests for payment. A false claim ordinarily must accompany or precede a claim for payment. See United States ex rel. Quinn v. Omnicare, 382 F.3d 432, 438-439 (3d Cir. 2004) (subsequent action or inaction cannot render previous claims false); Harrison, 176 F.3d at 787 (claim must be false when presented). A provider’s certification that it has complied with instructions pertaining to year-end cost reporting forms and schedules months or years *after* the claims at issue were submitted and paid, does

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<sup>19</sup> A real example of an obligation to note a departure from the cost reporting instructions might involve a failure to use the prescribed cost allocation methods in preparing cost report schedules.

not bootstrap an obligation to identify medical necessity issues arising under a separate and distinct billing system that predated the cost report. The district court's inclination that intermediaries should have been told somewhere that the hospitals billed for individual cases in a manner that conflicted with the Manual is not an adequate ground to invent a false certification in the annual cost report.

Additionally, the absence of any express false statement on any of the billing forms undermines the government's reliance on United States v. Weiss, 914 F.2d 1514, 1521 (2d Cir. 1990). In Weiss, durable medical equipment suppliers maximized their reimbursement by selectively billing the Medicare Carriers that paid the highest rates, in derogation of a transmittal that prescribed billing the Carrier for the beneficiary's residence. This Court declined to overturn defendants' convictions, even though the underlying transmittal had not been promulgated in compliance with the Paperwork Reduction Act. While DOJ cites Weiss for the proposition that a FCA claim may be brought against someone for circumventing even an unlawful manual provision, that was not this Court's holding. Weiss stressed that the prosecution was "not an action to enforce the" manual provision claimed to be unlawful, but rather a straightforward fraud case aimed at individuals who "cheated the government" by affirmatively misrepresenting the supplier's location (*i.e.*, deliberately using phony addresses) on the HFCA 1500 form. 914 F.2d at 1521, 1524. In the cases at bar, there were no affirmative false statements on any of the forms, the use of the IMDs was not intended to and did not result in any increase in the Medicare reimbursements, and DOJ is using the FCA to enforce an invalid Manual provision.

Contrary to the district court’s conclusion, the government does not lack recourse for perceived violations of a manual in the absence of a FCA remedy. Every case is subject to payment review by the intermediaries, who have free access to all hospital records (including medical records and invoices for devices) and may deny coverage if they deem a treatment unreasonable or unnecessary. The propriety of care being provided by hospitals to Medicare beneficiaries is further subject to scrutiny by peer reviewers under 42 U.S.C. § 1320c *et seq.*, and since 2003, by quality reviewers acting under 42 U.S.C. § 1395kk-1. Satisfaction of the requirements to provide medically necessary and appropriate services also is a condition of provider participation in Medicare (42 U.S.C. § 1320c-5). The suggestion that resort to the FCA is necessary here because there would be no other recourse to ensure compliance with an *invalid* manual (In re Cardiac Devices, 221 F.R.D. at 343) should be squarely rejected. This rationale improperly presumes that such provisions are binding and ignores that the hospitals billed for services that actually were covered (given the invalidity of the Manual and CMS’s re-affirmance of its original position in the 1995 rule).

**B. This Court Should Refuse To Recognize An “Implied False Certification” On These Facts**

The district court also erred in concluding that the “hospitals ... implicitly [falsely] certified that the services billed for were ‘reasonable and necessary’” under 42 U.S.C. § 1395y(a)(1)(A) by virtue of billing for these cases. 221 F.R.D. at 343.

First, this assertion is founded on the assumption that the claims “were not [medically necessary] according to the Manual provision that was binding on the hospitals (emphasis added).” *Id.* Regardless of whether the “wording” of the

1986 Manual provision was “clear and unambiguous” (*id.*), a long line of precedent discussed above repudiates DOJ’s claim that this provision was “binding” or had the “force and effect of law.”

Second, where, as here, the *final rule interprets* the statute as *covering* procedures as medically necessary (and as necessary to afford beneficiaries access to appropriate medical care), it is *that interpretation* against which the “implied certification” should be measured, *not* the interim guidance that has since been repudiated. See Monmouth Med. Ctr. v. Thompson, 257 F.3d 807 (D.C. Cir. 2001); In re Medicare Reimbursement Litig., 414 F.3d 7 (D.C. Cir. 2005), *reh’g. denied* (Sept. 28 2005) (CMS’s last and final clarification of the statute arrived at through a formal HCFA Administrator’s ruling should be viewed as the overriding interpretation of what the statute has always required).<sup>20</sup>

Medicare Reimbursement Litig. and Monmouth granted mandamus relief to afford providers the benefit of the Secretary’s latest interpretation of certain reimbursement rules. By analogy, defendants should not have to suffer coercive FCA suits when their failure to follow the 1986 Manual ultimately was vindicated by CMS’s repudiation of the Manual’s interpretation in the 1995 final rule. Once the 1995 rule was enacted (even before the complaint was unsealed), DOJ lost any valid basis to advance this claim because the rule mooted any claim of falsity. See also United States v. Munsingwear, Inc., 340 U.S. 36 (1950) (repeal of prior price

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<sup>20</sup> While an interpretive rule by definition has “retroactive” effect because it defines what a statute means, even substantive rules or statutes enacted during the pendency of litigation are applied retroactively where the revisions to the law do not burden private rights. Landgraf v. USI Film Products, 511 U.S. 244, 270 (1994). Here on the 1995 rule removed burdens to private rights.

control rule on which treble damages claim was based rendered moot, and required dismissal of, claim arising under for the superseded rule).

CMS's most contemporaneous interpretation of the Act represented by IL No. 77-4, *supra*, deemed inpatient services that included IMDs to be reasonable and necessary. When the agency *re-visited* the issue through formal rulemaking in 1995, it concluded again that virtually all of the devices here at issue should be deemed medically reasonable and necessary. Any "implied certification" of medical necessity could be deemed "false" only if the Court were to ignore the agency's formal and final interpretation of the 1965 statute in the 1995 final rule. Unlike the interim 1986 Manual, the 1995 rule represents an agency interpretation of the "reasonable and necessary" standard to which judicial deference *is* due under Mead and Christensen. CMS should not be afforded the flexibility to refine or alter its interpretation of law subject to judicial deference under Chevron, while the DOJ is simultaneously permitted to ignore that interpretation, and pursue coercive FCA prosecutions to enforce the interpretation CMS has repudiated.

Even aside from the 1995 rule, this Court should eschew DOJ's FCA prosecutions on the theory that hospitals intentionally breached an "implied certification" that they were billing Medicare for medically necessary services. In Mikes, a relator alleged that physicians billing Medicare Part B for certain tests without calibrating their equipment had impliedly falsely certified that the tests were "medically necessary" to obtain payments prohibited by § 1395y(a)(1)(A). This Court rejected the implied certification theory on the facts, and cautioned against "reading this theory expansively and out of context," particularly where it would "promote federalization of medical malpractice." Id. at 699, 700. The Court

indicated in *dicta* that a provider might be sued under the FCA for a false implied certification in “limited circumstances,” and “only when the underlying statute or regulation on which plaintiff relies *expressly* states that” compliance is a precondition to payment. *Id.* at 700 (underline added; italics in original).<sup>21</sup> This Court strongly cautioned against using the FCA as a “blunt instrument” to enforce compliance with issues of medical necessity and regulatory standards pertaining to the quality of care, especially in view of other statutory provisions, such as 42 U.S.C. § 1320c-5(a), specifically designed to regulate whether a service “meets professionally recognized standards of health care.” *Id.* at 699, 701.

Here, the “underlying statute” provides that services must be “reasonable and necessary” for the treatment of illness or disease. No “*statute or regulation*” prohibits billing Medicare for treatments that include IMDs. This Court should not extend the implied certification theory to a case in which *only a manual* states a condition with which providers must comply. It should draw this line not only because manuals – unlike “statutes and regulations” – are not “legally binding,” but because the 1986 Manual inappropriately purported to “resolve medical issues concerning levels of care” that should only be resolved with input from “medical agencies, boards and societies.” *Id.* at 700.

Congress has considered statutory amendments to curb DOJ’s increasingly aggressive use of the FCA as a weapon against health care providers. See Health

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<sup>21</sup> See also Quinn, 382 F.3d at 442; U.S. ex rel. Luckey v. Baxter Healthcare Corp., 183 F.3d 730 (7th Cir. 1999); U.S. ex rel Siewick v. Jamieson Sci. & Eng’g, Inc., 214 F.3d 1372, 1376 (D.C. Cir. 2000); United States ex rel. Thomas v. Columbia/HCA Healthcorp., 125 F.3d 899, 902 (5th Cir. 1997) (all rejecting FCA claims based on implied certification of regulatory compliance).



Care Claims Guidance Act, S. No. 2007 and H.R. No. 3523, 105<sup>th</sup> Cong. (1998).<sup>22</sup>

Suing hospitals under the FCA to enforce an invalid guidance that has already been repudiated in formal rulemaking crosses the line from appropriate vigor into coercive zeal. This Court should firmly reject DOJ's efforts to expand the implied certification envelope to include cases like these.

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<sup>22</sup> See also Ohio Hosp. Ass'n v. Shalala, 201 F.3d 418 (6th Cir. 1998) (noting “heavy handed” use of reckless disregard standard “to threaten a . . . hospitals with draconian penalties” to exact settlements for billing errors for outpatient laboratory tests); United States v. Krizek, 7 F. Supp. 2d 56, 60 n.4 (D.D.C. 1998) (criticizing “overzealous” use of the FCA against health care providers).

## CONCLUSION

For the reasons stated above, Amici support the position of Appellants and respectfully request that the Court reverse the order below and remand the case with instructions to dismiss the FCA claims against defendants.

Respectfully submitted,

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<sup>23</sup> Counsel wish to acknowledge the contributions to the brief by Melanie K. Martin, who is awaiting formal swearing in by the Pennsylvania Supreme Court.

**CERTIFICATE OF COMPLIANCE  
WITH FED. R. APP. P. 29(D) AND 32(A)**

This brief complies with the type-volume limitations of Fed. R. App. P. 29(d) and 32 (a) (7) (B) because it contains approximately 6,890 words, excluding the parts of the brief exempted by Fed. R. App. 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) (5) because this brief has been prepared in 14 point proportional roman typeface.

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**CERTIFICATE OF SERVICE**

I hereby certify that on this 21<sup>st</sup> day of October 2005, I caused two copies of the foregoing Brief for Amici Curiae in Support of Appellants to be served by Federal Express on each of the following:

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