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THE PATIENT PROTECTION AND AFFORDABLE CARE ACT OF 2010: RULEMAKING IN THE SHADOW OF INCENTIVE-BASED REGULATION

SAM FOSTER HALABI¹

I. Introduction: The Space Between Judicial Review of the Affordable Care Act and Delegated Authority to Administrative Agencies

The federal courts are unevenly divided in their treatment of the initial constitutional challenges to the Patient Protection and Affordable Care Act of 2010 (“Affordable Care Act”). Two district judges have ruled that the individual mandate provision of the law exceeds Congress’s constitutional authority and one has struck down the law in its entirety.² Many more district judges have used the *Twombly* and *Iqbal*-emboldened Federal Rule of Civil Procedure 12(b)(6) to turn away similar challenges across the country.³ Although the question is years from final resolution, it appears that the 111th Congress internalized U.S. Supreme Court decisions limiting its power under the Commerce Clause, anticipating constitutional challenges to the individual mandate to purchase health insurance, Medicaid expansion and insurance exchange regimes and structuring the law to survive those challenges.⁴ The majority of the district judges who are meticulously combing through the 2700-plus page legislation, holding hearings and carefully weighing well-funded and sophisticated

¹ Assistant Professor, University of Tulsa College of Law. J.D. Harvard, 2005; M.Phil. Oxford, 2001; B.A. B.S. Kansas State University, 1999. The author would like to thank two anonymous reviewers for comments.

² On March 23, 2010, President Obama signed into law the Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119. U.S. District Judge Henry Hudson ruled that the individual mandate exceeded Congress’s authority under the Commerce Clause and could not be characterized as a tax. *Virginia v. Sebelius*, No. 3:10CV188HEH (E.D. Va. Dec. 13, 2010). Judge Vinson struck down the law in its entirety. *Florida v. Dep’t of Health and Human Services*, No. 3:10-cv-91-RV/EMT (N.D. Fla. Jan. 31, 2010)

³ See e.g. *Florida v. Dep’t of Health and Human Services*, No. 3:10-cv-91-RV/EMT (N.D. Fla. Oct. 14, 2010); Thomas More Law Ctr. v. Obama, No. 2:10-cv-11156-GCS-RSW (E.D. Mich. Oct. 7, 2010); Kevin Sack, *Judge Rules Health Care Law is Constitutional*, N.Y. TIMES, Oct. 8, 2010, available at

http://www.nytimes.com/2010/10/08/health/policy/08health.html?_r=1; See also Timothy Jost, *Examining Judge Hudson’s Decision on the Individual Mandate*, HEALTH AFFAIRS BLOG,

<http://healthaffairs.org/blog/2010/12/14/examining-judge-hudsons-decision-on-the-individual-mandate/>

⁴ See e.g. *United States v. Lopez*, 514 U.S. 549 (1995); *United States v. Morrison*, 529 U.S. 598 (2000).

arguments from multiple constituencies probably have it right.⁵ Whatever the novelty and reach of the Affordable Care Act, it requires a narrow reading of the Constitution and U.S. Supreme Court precedent to decide – to name two possibilities – that the individual mandate does not rationally serve Congress’s plan for regulating access to health insurance or that tying so much of the reform law to Medicaid expansion constitutes the only known example of Congress impermissibly coercing the States with its implied spending power.⁶ These fights will undoubtedly return in various forms where other difficult constitutional questions are likely to arise. Specifically, there will be debates about the substantial powers Congress delegated to regulatory agencies – primarily the Secretary of Health and Human Services – and the deference the courts will show those agencies in light of applicable U.S. Supreme Court decisions.⁷ For example, Richard Epstein has argued that the Affordable Care Act’s “standardless” delegation of authority to the Secretary of HHS to set essential benefits packages and monitor premium increases is tantamount to transforming health insurance providers into public utilities.⁸ Between facial constitutional challenges to the Affordable Care Act and lawsuits based on defects in agency rules or the rulemaking process lies the significant discretionary area in which the Secretary of HHS, and others, will make the most important implementation decisions. This Article is intended to provide agencies guidance for shaping the rules that Congress clearly intended them to adopt and implement, but which courts are less likely to question. This article argues that (1) Congress demonstrated a strong intent for private enforcement of the Affordable Care Act’s provisions (especially those expanding Medicare and Medicaid benefits and eligibility); (2) Congress concurrently included enhancements for private enforcement of governmental payments programs in the Fraud Enforcement and Recovery Act⁹ and the Dodd-Frank Wall Street Reform and Consumer Protection Act¹⁰; and, therefore, (3) administrative agencies should structure rules to facilitate private enforcement. The argument proceeds as follows. Congress, determining that markets (money incentives) are smarter than people (salaried regulators), expanded the circumstances under which it would pay private citizens to root out and report improper or fraudulent activity against the taxpayers.¹¹ Because those circumstances are likely to apply across a wide range of industry sectors, Congress included the enhancements in different legislative acts. Administrative agencies, especially those overseeing government payments programs, will advance Congressional mandates for efficiency and effective enforcement by shaping rules with the aim of facilitating private enforcement. Toward that end, agencies should look beyond the immediate charging statute for guidance.

II. Medicare, Medicaid and CHIP: Overpayment, Fraud and the Affordable Care Act

⁵ See Brendon Farrington, *White House, experts: Health care suit will fail*, ASSOCIATED PRESS (Mar. 23, 2010), available at <http://www.signonsandiego.com/news/2010/mar/23/white-house-experts-health-care-suit-will-fail/>.

⁶ U.S. CONST. art. I, § 8, cl. 3; See *South Dakota v. Dole*, 483 U.S. 203 (1987).

⁷ See *Chevron U.S.A., Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837 (1984); *Skidmore v. Swift & Co.*, 323 U.S. 134 (1944); *Christensen v. Harris County*, 529 U.S. 576 (2000).

⁸ Richard Epstein, *Impermissible Rulemaking in Health-Insurance Reform: Why the Reid Bill is Unconstitutional*, POINT OF LAW, Dec. 18, 2009, available at <http://www.pointoflaw.com/columns/archives/2009/12/impermissible-ratemaking-in-he.php>.

⁹ Fraud Enforcement and Recovery Act, Pub. L. No. 111-21, 123 Stat. 1617 (2009).

¹⁰ Wall Street Reform and Consumer Protection Act, Pub. L. No. 111-203, 124 Stat. 1376 (2010).

¹¹ This division is of course somewhat simplistic. The “revolving door” between administrative agencies and consulting, law and lobbying firms (to say nothing of the regulated firms themselves) located at centers of political decision-making means that regulators will inevitably fashion rules with the knowledge that in the near or distant future they might rely upon those firms for sometimes highly paid employment.

With respect to the Affordable Care Act, this argument is applicable to the problems of fraud and abuse that will inevitably accompany the expansion of health entitlements. The most important health care entitlement programs are Medicare, Medicaid and the Children's Health Insurance Program ("CHIP"). Generally, Americans who are 65 years old or younger and disabled are eligible for Medicare. Medicare is administered by the federal government and is broken into different parts. Medicare Part A covers hospital insurance.¹² Medicare Part B provides insurance against the costs of certain outpatient services administered by a physician during an office visit as well as "durable medical equipment" like walkers and wheelchairs.¹³ Medicare Part C (or Medicare Advantage) allows private insurers to provide care at the same level as Medicare, but allows certain flexibilities in coverage and provider choice that may lower costs for recipients.¹⁴ Medicare Part D subsidizes the cost of prescription drugs but does so through private plans that do not offer systematically standardized coverage.¹⁵ Medicaid is the joint federal-state program that is aimed at providing health care to low-income individuals and families. Medicaid is funded jointly by the federal and state governments, but states administer the program and determine guidelines for eligibility and service provision.¹⁶ CHIP is aimed at providing health insurance coverage for children in families with modest incomes that are nevertheless too high for Medicaid eligibility. Its administrative structure closely resembles Medicaid's.¹⁷

The Affordable Care Act expands eligibility for Medicaid to those making 133% of the federal poverty line and requires States to add childless adults to the eligible population.¹⁸ Previously, a recipient could not qualify only by virtue of low income. Medicaid only helped those who were at or below the poverty line and had met another requirement – typically pregnancy, disability, age or having minor dependents.¹⁹ The Affordable Care Act will increase those eligible for Medicaid from 60 million to somewhere between 75 million and 78 million.²⁰ The law also adds certain benefits to Medicare and CHIP eligible individuals and families.²¹

¹² Medicare Part A (Hospital Insurance), <http://www.medicare.gov/navigation/medicare-basics/medicare-benefits/part-a.aspx>.

¹³ Medicare Part B (Medical Insurance), <http://www.medicare.gov/navigation/medicare-basics/medicare-benefits/part-b.aspx>.

¹⁴ Medicare Advantage (Part C), <http://www.medicare.gov/navigation/medicare-basics/medicare-benefits/part-c.aspx>.

¹⁵ What is Part D (Medicare Prescription Drug Coverage), <http://www.medicare.gov/navigation/medicare-basics/medicare-benefits/part-d.aspx>.

¹⁶ See Overview Medicaid Program, CENTERS FOR MEDICARE & MEDICAID SERVICES, <http://www.cms.gov/MedicaidGenInfo/>.

¹⁷ See Overview of National CHIP Policy, CENTERS FOR MEDICARE & MEDICAID SERVICES, <http://www.cms.gov/NationalCHIPPolicy/>.

¹⁸ Pub. L. No. 111-148, § 2001 (a) (1). The law adds an 8th categorical eligibility: those who are under 65 years of age, not pregnant, not entitled to or enrolled for Medicaid benefits under another category. The law establishes eligibility at 133% of federal poverty level, but allows for an additional 5% modified adjusted gross income.

¹⁹ See *id.*

²⁰ With respect to the number of new Medicaid enrollees, the numbers vary with source. The Congressional Budget Office estimated that the expansion would increase the number of enrollees in Medicaid and the Children's Health Insurance Program by about 15 million, costing states about \$26 billion over 10 years. The Centers for Medicare and Medicaid Services estimated that the law would add 18 million people on the Medicaid beneficiary list. An additional 2 million with employer-sponsored health insurance would enroll in Medicaid for supplemental coverage. The Henry J. Kaiser Family Foundation, a group that analyzes health care policy, estimated that Medicaid would enroll as many as 17.1 million new beneficiaries under the health care bill.

²¹ See e.g. Centers for Medicare & Medicaid Services, *Medicare and the New Health Care Law – What it Means for You* (May 2010), available at <http://www.medicare.gov/Publications/Pubs/pdf/11467.pdf>.

All stakeholders fear that the increased entitlements will cause negligent and fraudulent overpayments under the programs to increase. In 2008, the FBI arrested doctors and patients who submitted over 140,000 false claims for pretending to receive expensive HIV- drug treatments.²² On October 13, 2010, federal and state law enforcement officials indicted 44 individuals for billing Medicare for over \$100 million for “services” that were never provided at phantom clinics.²³ One pharmacist bilked Medicaid for over \$1.8 million in less than a year by submitting phony claims for prescriptions that he never filled.²⁴ Yet not all of the improprieties are so sensational. Because Medicaid and Medicare “pay and chase” – that is, reimburse claims as a matter of course and then pursue improper billing later – millions of dollars are also lost for services, drugs, or supplies that are unnecessary, not performed or are of a lower quality or more costly than those that are actually performed.²⁵ “Major corporations such as pharmaceutical and medical device manufacturers and institutions such as hospitals and nursing facilities have also committed fraud, sometimes on a grand scale.”²⁶ Physicians may refer patients to providers with whom they share a financial interest and create incentives to raise costs or pay kick-backs, but Congress has curtailed such practices with the so-called Stark Law.²⁷ In addition, providers benefit from what appear to be even benign mistakes. For example, charging a patient for an “office visit” when he or she only visited for a flu shot, is a tactic known as “upcoding” that results in a higher reimbursement for the health care provider.²⁸ Sensing that the known difficulties of monitoring reimbursements under Medicare and Medicaid might present opponents with arguments against expansion of entitlements, Congress included measures to more effectively screen applicants for Medicare and Medicaid participation, encourage information sharing across law enforcement agencies and toughen penalties and the means by which they are collected.

III. The Regulatory Structure of Medicare, Medicaid and CHIP

Medicare and Medicaid providers are regulated generally by the Department of Health and Human Services (“HHS”) and specifically by the Centers for Medicare and Medicaid Services (“CMS”) which oversee enrollment, reimbursement, monitoring and enforcement policies applicable to health care providers under Medicare, Medicaid and CHIP.²⁹ Both the HHS Office of the Inspector General and CMS also maintain integrity units that investigate reimbursement patterns and individual claims to detect billing errors and unusual medical treatment. Under the Medicaid

²² Carrie Johnson, *Medical Fraud a Growing Problem*, WASH. POST (June 13, 2008), available at http://www.washingtonpost.com/wp-dyn/content/article/2008/06/12/AR2008061203915_2.html.

²³ Press Release, Dep’t. of Justice, Manhattan U.S. Attorney Charges 44 Members and Associates of an Armenian-American Organized Crime Enterprise with \$100 Million Medicare Fraud (Oct. 13, 2010), available at <http://newyork.fbi.gov/dojpressrel/pressrel10/nyfo101310.htm>.

²⁴ Melissa Grace, *Pharmacist Patrick Alcindor Stole \$18 million from Taxpayers in Medicaid Fraud Scheme*, N.Y. DAILY NEWS (Nov. 4, 2010), available at http://www.nydailynews.com/ny_local/2010/11/04/2010-11-04_pharmacist_patrick_alcindor_stole_18m_from_taxpayers_in_medicaid_fraud_scheme_la.html.

²⁵ See Dept. of Health and Human Services, Centers for Medicare and Medicaid Services, 75 Fed. Reg. 58238 (proposed Sept. 23, 2010).

²⁶ *Testimony of Daniel R. Levinson, Inspector General, U.S. Dep’t. of Health & Human Services*, Mar. 4, 2010, available at <http://oig.hhs.gov/testimony/docs/2010/3-4-10LevinsonHAppropsSub.pdf>.

²⁷ 42 U.S.C. § 1395nn; 42 C.F.R. §§411.350-411.389.

²⁸ U.S. DEP’T OF HEALTH AND HUMAN SERVICES, CENTERS FOR MEDICARE & MEDICAID SERVICES, MEDICARE CLAIMS PROCESSING MANUAL, at 12, available at <http://www.cms.gov/manuals/downloads/clm104c18.pdf>.

²⁹ Law enforcement agencies at the federal and state level also work with the HHS OIG and CMS.

program, states also maintain fraud control units to monitor payments to providers.³⁰ Yet CMS concedes that the job is overwhelming.³¹ In 2008, CMS reviewed less than 5% of Medicare claims.³² State Medicaid reviewers are similarly inundated.³³

CMS adopts some form of command-and-control, performance standard and incentive-based regulation as part of administering Medicare, Medicaid and CHIP.³⁴ These categories provide a useful taxonomy by which to understand theories of regulation even if in practice the line between them blurs and some forms of regulation might fall outside of these neat descriptions. Loosely defined, command-and-control rules impose specific requirements on regulated firms. For instance, a polluter might be required to adopt a particular type of technology designed to limit the quantity of pollution. Performance-based standards tell firms what they must accomplish but leave them to decide how best to do so. Such a standard, for example, might specify the maximum quantity of pollution that a firm may produce without specifying the means by which the firm is required to comply. Finally, incentive-based systems force firms to internalize the total costs of their activities, leaving firms to decide what, if anything, to do about those costs.³⁵ CMS, for example, now requires a provider to have a compliance and ethics program in place “that is effective in preventing and detecting criminal, civil, and administrative violations and in promoting quality care . . .”³⁶ Performance standards are imposed to varying degrees on providers of specific services in order to qualify for participation in Medicare and Medicaid.³⁷ For example, a state may require that providers of certain services or durable medical equipment meet established financial or health outcome criteria in order to continue participating in the Medicaid program.³⁸ Incentive-based regulation in these programs takes two primary forms: the False Claims Act and Recovery Audit Contractors.

IV. Incentive-based Regulation in the Medicare and Medicaid Programs

A. The False Claims Act

³⁰ U.S. DEP’T. OF HEALTH & HUMAN SERVICES, OFFICE OF INSPECTOR GENERAL, MEDICAID FRAUD CONTROL UNITS (MFCU), available at <http://oig.hhs.gov/fraud/mfcu>.

³¹ Johnson, *supra* note 23.

³² *Id.*

³³ See e.g. John Lyon, *Lawmakers review Medicaid audit*, ARKANSAS NEWS, April 9, 2010, available at <http://arkansasnews.com/2010/04/09/lawmakers-review-medicaid-audit/>; Tyley Whitley, *Va. Medicaid paid out \$39 million improperly in fiscal 2009*, RICHMOND TIMES-DISPATCH, Oct. 13, 2010, available at <http://www2.timesdispatch.com/news/2010/oct/13/medi13-ar-559304/>.

³⁴ Kimberly Brandt, Director, Program Integrity Group, U.S. Dep’t. of Health and Human Services, Testimony before Committee on Ways and Means on Reducing Fraud, Waste and Abuse in Medicare (June 15, 2010), available at <http://www.hhs.gov/asl/testify/2010/06/t20100615a.html>.

³⁵ See Jon Hanson & Kyle Logue, *The Costs of Cigarettes: The Economic Case for Ex Post Incentive-Based Regulation*, 107 YALE L.J. 1163, 1173-74 (1998).

³⁶ Dept. of Health and Human Services, Centers for Medicare and Medicaid Services, 75 Fed. Reg. 58238 (proposed Sept. 23, 2010).

³⁷ See U.S. DEP’T OF HEALTH AND HUMAN SERVICES, CENTERS FOR MEDICARE & MEDICAID SERVICES, PROVIDER ENROLLMENT REGULATION, available at https://www.cms.gov/MedicareProviderSupEnroll/09_ProviderEnrollmentRegulation.asp.

³⁸ James W. Fossett et. al., *Managing Medicaid Managed Care: Are States Becoming Prudent Purchasers?*, 19 HEALTH AFFAIRS 36 (2000).

Incentive-based regulation in the Medicare and Medicaid programs is both old and new. Claims submitted to either program are subject to private litigation under the False Claims Act (“FCA”).³⁹ Enacted during the Civil War to combat fraud on the Union army, the FCA is the United States’ primary tool for fighting fraud directed against the public coffers.⁴⁰ Under the False Claims Act regime, private citizens (“whistleblowers” or “relators”) work closely with the U.S. Department of Justice to identify inappropriate claims submitted to the government for payment.⁴¹ In 1986, Congress strengthened its *qui tam* provisions to allow whistleblowers to file suit under seal on behalf of the United States and share up to 30 percent of the United States’ ultimate recovery.⁴² While the *qui tam* complaint is under seal, and before it is served on the defendant, the United States Department of Justice investigates to decide whether to intervene and take over the prosecution of the action or decline to intervene and allow the whistleblower to proceed.⁴³ The United States is the real party in interest, even in cases where it declines.⁴⁴ The FCA establishes liability for any person who knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval.⁴⁵ “Knowledge” is defined broadly to include actual knowledge, deliberate ignorance of the truth, or reckless disregard of the truth. A corporation is deemed to have knowledge if its employee acted knowingly.⁴⁶ Whistleblower suits initiated under the FCA between 1987 and 2008 have resulted in the return of approximately \$22 billion in improper payments and damages.⁴⁷

1. The Affordable Care Act Encourages the Use of the FCA to Combat Fraud

The Affordable Care Act explicitly expanded access to private litigants suing under the FCA. First, Congress directly linked the retention of overpayments to false claim liability. Under the Affordable Care Act, “overpayments” are defined as “any [Medicare or Medicaid] funds that a person receives or retains . . . to which the person, after applicable reconciliation, is not entitled.”⁴⁸ Health care providers, suppliers, Medicaid managed care organizations, Medicare Advantage organizations and drug plan sponsors must “report and return” any overpayments within 60 days after either the date on which the overpayment was identified or the date any corresponding cost report was due, whichever is later.⁴⁹ In addition, members of the health care industry must submit notification in writing to the entity to which the overpayment was returned as to the reason of the overpayment.⁵⁰

³⁹ 31 U.S.C. § 3729, *et seq.* (2010).

⁴⁰ *See* United States ex rel. Marcus v. Hess, 317 U.S. 537, 551 (1943).

⁴¹ *Id.*

⁴² False Claims Act Amendments Pub. L. No. 99-562, 100 Stat. 3153. The U.S., in turn, is awarded treble damages and can impose civil fines between \$5,000 and \$10,000 per claim. The phrase “*qui tam*” is an abbreviated form of *qui tam pro domino rege quam pro se ipso in hac parte sequitur*, is translated by Blackstone as “who prosecutes this action for the king, etc. as for himself.” In the English common law, the writ was historically available to citizens to enforce the king’s laws. 4 WILLIAM BLACKSTONE, COMMENTARIES ON THE LAWS OF ENGLAND 1154 (1765).

⁴³ *See* FED. R. CIV. P. 17.

⁴⁴ *See id.*

⁴⁵ 31 U.S.C. § 3729.

⁴⁶ *See, e.g.*, United States v. Entin, 750 F. Supp. 512, 518 (S.D. Fla. 1990); *cf.* Gleason v. Seaboard Air Line Ry. Co., 278 U.S. 349 (1929).

⁴⁷ JACK A. MEYER, ECONOMIC AND SOCIAL RESEARCH INSTITUTE, FIGHTING MEDICARE FRAUD: MORE BANG FOR THE FEDERAL BUCK (July 2006), available at <http://www.taf.org/FCA-2006report.pdf>.

⁴⁸ Pub. L. No. 111-148, 124 Stat. 119 (2010).

⁴⁹ *Id.*

⁵⁰ *Id.*

Second, Congress used the Affordable Care Act to expand access to whistleblowers who identify fraudulent practices by allowing them to use publicly disclosed information. Previously, such information was unavailable to them due to limiting court decisions that fashioned a “Public Disclosure Bar” to claims that relied in significant part on publicly available information.⁵¹ Section 10104(j)(2) of the law replaces the prior version § 3730(e)(4) of the FCA with new language that expands the scope of the original source exception and shifts the Public Disclosure Bar from a jurisdictional prohibition to a more flexible standard, with discretionary power held by the government.⁵² One important effect of the change is to enable whistleblowers to use information available from a state Medicaid hearing or process in order to establish a claim under the FCA.⁵³ These FCA amendments are not limited to *qui tam* cases involving federal health care programs.⁵⁴

2. Congress Concurrently Enacted FCA Enhancements in the Fraud Enforcement Recovery Act and the Dodd-Frank Wall Street Reform and Consumer Protection Act

In the Fraud Enforcement and Recovery Act of 2009 (“FERA”), Congress included enhancements to the FCA. Most significantly for purposes of Medicare and Medicaid, Congress expanded the number of actors upon whom fraud would support a “claim” under the FCA; included the retention of government overpayments as a basis for FCA liability; broadened the scope of conspiracy under the FCA; enhanced protections for whistleblowers against retaliation; and, bolstered the government’s investigative powers.⁵⁵ For example, under judicial interpretations of the FCA prior to FERA, a skilled nursing facility might contract out certain physical therapy treatments.⁵⁶ Because the physical therapy provider did not directly submit claims to Medicare or

⁵¹ See *Graham County Soil v. U.S.*, 130 S. Ct. 1396 (2010). The amendments legislatively overruled *Graham County Soil v. U.S.* in which the U.S. Supreme Court decided that the public disclosure bar was intended to limit whistleblowers' ability to use secondhand information to generate false claims cases.

⁵² Under § 10104(j)(2) of the Affordable Care Act, the government now has the ability to control whether a *qui tam* complaint is dismissed based on publicly disclosed information. Section 10104(j)(2) provides:

Section (4)(A). The court shall dismiss an action or claim under this section, unless opposed by the Government, if substantially the same allegations or transactions as alleged in the action or claim were publicly disclosed: (i) in a Federal criminal, civil or administrative hearing in which the Government or its agent is a party; (ii) in a Congressional, Government Accountability Office, or other Federal report, hearing, audit or investigation; or (iii) from the news media, unless the action is brought by the Attorney General or the person bringing the action is an original source of the information.

The Affordable Care Act also narrows the definition of publicly disclosed information and expands the scope of the original source exception. The new language also widens the definition of an “original source” by eliminating the requirement that a whistleblower have “direct” knowledge of facts underlying his or her allegations. A *qui tam* whistleblower need only have “knowledge that is independent of and materially adds to the publicly disclosed allegations” Under the new law, a whistleblower’s allegations can now be based on indirect information, provided those allegations add to information that is already contained in the public domain. The public disclosure must also result from a federal report, hearing, audit or investigation. Public disclosures in state or local government reports also no longer bar the whistleblower’s claim.

⁵³ *Id.*

⁵⁴ *Id.*

⁵⁵ Fraud Enforcement and Recovery Act of 2009, Pub. L. No. 111-21, 123 Stat. 1617. FERA rolled back judicial decisions that had limited the FCA’s reach, including *Allison Engine Co. v. United States ex rel. Sanders*, 128 S. Ct. 2123 (2008); *United States ex rel. Totten v. Bombardier Corp.*, 380 F.3d 488 (D.C. Cir. 2004), *cert. denied*, 544 U.S. 1032 (2005); and *United States ex rel. DRC, Inc. v. Custer Battles, LLC*, 376 F. Supp. 2d 617 (E.D. Va. 2005), *rev’d*, 562 F.3d 295 (4th Cir. 2009).

⁵⁶ David S. Barmak, *Providers/suppliers beware: expansion of the False Claims Act*, LEXOLOGY, Nov. 1, 2010, available at <http://www.lexology.com/library/detail.aspx?g=32d3b9a3-1ce9-4cd8-9f22-27ee7c847328>.

Medicaid, an FCA claim could not prevail against the therapist.⁵⁷ The amendments to the law corrected this defect.

In the Dodd-Frank Wall Street Reform and Consumer Protection Act (“financial reform law”), Congress created a uniform three-year statute of limitations period for claims of retaliation by whistleblowers and widened FERA’s definition of acts protected by the retaliation cause of action.⁵⁸ These measures demonstrate an identifiable intent from Congress to use “private attorneys general” in the expanding areas in which government payments are made and might be fraudulently obtained.

B. Recovery Audit Contractors

In 2003, Congress required Medicare (not Medicaid) to enact a pilot program whereby private auditing entities – recovery audit contractors (“RACs”) – would be given incentive to hunt down overpayments or improper billing submissions by health care providers.⁵⁹ RACs typically review a sample of a health care provider’s claims for a given period and determine an error rate. RACs then generalize the error rate over the universe of claims during the audit period to calculate an alleged overpayment amount.⁶⁰ The amount sought to be recouped by CMS based on the extrapolation from a relatively small sample of claims billed can be large. The RACs are paid a contingency fee based on the overpayment amount, which may provide their auditors with an incentive to find claims that they contend should have been denied. Between 2005 and 2007, the private auditors returned \$693.6 million to the Medicare Trust Funds.⁶¹ The Affordable Care Act expanded RAC contracting to all Medicare programs and required States to contract with RACs for Medicaid audits.⁶² As with FERA and the financial reform law, the expansion of the RAC program shows a clear mandate from Congress to mobilize incentive-based regulation of healthcare providers that submit claims for reimbursement under Medicare and Medicaid.

V. Rulemaking in the Shadow of Incentive Based Regulation

A. CMS Cannot Effectively Monitor Fraud and Waste with Current or Promised Resources

Prior to the passage of the Affordable Care Act, the General Accounting Office issued regular reports which indicated that CMS could not keep pace with enforcement demands. On June 28, 2005, the GAO reported that CMS had only 8 employees devoted to chasing down improper Medicaid billing.⁶³ On March 3, 2010, the GAO reported that between 2005 and 2008, CMS had failed to ensure that Medicare Part D drug plan providers had implemented policies to prevent and

⁵⁷ *Id.*

⁵⁸ See 31 U.S.C. §3730(h).

⁵⁹ U.S. DEP’T OF HEALTH AND HUMAN SERVICES, CENTERS FOR MEDICARE & MEDICAID SERVICES, REVIEW AUDIT CONTRACTOR OVERVIEW, available at <https://www.cms.gov/RAC/>.

⁶⁰ Deborah J. Juneau, *Recovery Audit Contractor Program Will Be Expanded to Medicaid*, LOUISIANA LAW BLOG, Sept. 2, 2010, <http://www.louisianalawblog.com/health-law-recovery-audit-contractor-program-will-be-expanded-to-medicare.html>.

⁶¹ Press Release, Dep’t. of Health & Human Services, Centers for Medicare & Medicaid Services, New Report Shows CMS Pilot Program Saving Nearly \$700 Million in Improper Medicare Payments (July 11, 2008), available at http://mailcenter.newmediagateway.com/healthport/files/flash_docs/public/0/RAC_press_release.pdf.

⁶² *Id.*

⁶³ U.S. GEN. ACCOUNTING OFFICE, MEDICAID FRAUD AND ABUSE: CMS’S COMMITMENT TO HELPING STATES SAFEGUARD PROGRAM DOLLARS IS LIMITED (2005), available at <http://www.gao.gov/new.items/d05855t.pdf>.

catch fraud and waste.⁶⁴ The same month, GAO reported that even where RACs had identified weaknesses in provider billing processes, CMS failed to act on its recommendations.⁶⁵ The GAO reports focus generally on the universe of command-and-control and performance standards regulations that are in place but have not been implemented because the HHS OIG or CMS are unable – by virtue of resource scarcity – to coordinate or enforce.

With the passage of the Affordable Care Act, Congress increased the budget for HHS's oversight activities by approximately \$35 million per year for ten years and mandated the development of better screening and data-sharing processes.⁶⁶ Yet these enhancements will not realize their intended effect if enforcement activity is centered in the regulatory agency instead of using whistleblowers and RACs to facilitate actions by regulators and prosecutors. Fraud and waste are the natural effect of rent-seeking market actors who are exploiting a system whose resource constraints limit its policing ability. The historical lesson is that similarly motivated market actors are most effectively positioned to root out fraudulent or inaccurate billing practices.

B. HHS and CMS Should Shape Rules to Facilitate Incentive-Based Regulatory Mechanisms

When developing and implementing regulations, administrative agencies should explicitly consider Congress's efforts to force health care providers to internalize the costs related to overbilling and mistakes, even if that authority lies outside an immediate charging statute. This consideration includes but is not limited to (1) interpreting statutes in order to maximize the opportunity for private enforcement and (2) coordinating instructional materials and billing practices in order to avoid conflicts with private litigants (or the Department of Justice with whom whistleblowers coordinate).

1. Drafting Rules from the Perspective of Private Enforcement

Potential whistleblowers and RACs are likely to (1) know the exact wording of statutes and regulations well and (2) give the text of statutes and regulations a strict reading in order to increase the incidence of overbilling and the size of their awards. Rule-making in the shadow of incentive-based regulation counsels HHS and CMS to take measures that give effect to the clear intent of Congress (both inside and outside the Affordable Care Act) to promote these strict readings.

Consider the example of the Affordable Care Act's provisions prohibiting health care providers from retaining overpayments. The law states that any overpayment retained after the deadline becomes an "obligation" for purposes of the FCA.⁶⁷ Therefore, a failure to return any Medicare or Medicaid overpayments by the deadline may result in FCA liability. In order to avoid such liability, CMS will inevitably require health care providers and other entities receiving reimbursement under

⁶⁴ U.S. GEN. ACCOUNTING OFFICE, MEDICARE PART D: CMS OVERSIGHT OF PART D SPONSORS' FRAUD AND ABUSE PROGRAMS HAS BEEN LIMITED, BUT CMS PLANS OVERSIGHT EXPANSION (2010), *available at* <http://www.gao.gov/products/GAO-10-481T>.

⁶⁵ U.S. GEN. ACCOUNTING OFFICE, MEDICARE AUDIT CONTRACTING: WEAKNESSES REMAIN IN ADDRESSING VULNERABILITIES TO IMPROPER PAYMENTS, ALTHOUGH IMPROVEMENTS MADE TO CONTRACT OVERSIGHT (2010), *available at* <http://www.gao.gov/new.items/d10143.pdf>.

⁶⁶ Press Release, U.S. Dep't. of Health & Human Services, HHS Secretary Sebelius, U.S. Attorney General Holder Kick-Off First Regional Health Care Fraud Prevention Summit in Miami, Florida (July 16, 2010), *available at* <http://www.hhs.gov/news/press/2010pres/07/20100716a.html.s>

⁶⁷ Pub. L. No. 111-148, 124 Stat. 119 (2010).

Medicare or Medicaid to implement policies and procedures on reporting and returning overpayments that are consistent with the requirements in the Affordable Care Act. CMS will also have to adopt regulations that govern those policies.

The statutory language itself does not give guidance as to when an overpayment is “identified” and the position likely to be taken by providers’ counsel is that overpayment has not been “identified” until the provider has “(1) absolutely concluded that there is an overpayment and (2) ascertained the amount of the overpayment.”⁶⁸ The narrower reading likely to be given by whistleblowers is that an overpayment has been “identified” where there is much less than an “absolute conclusion” and well before an exact amount has been precisely calculated. The narrower reading is more consistent with Congress’s actions in concurrent legislation expanding whistleblowers’ access to the courts under the FCA.

a. Early Signs that CMS will not Rely on Incentive-Based Regulation: The Self-Reporting Disclosure Protocol under the Stark Law

Early guidance, protocols and rules proposed by HHS and CMS instead seem to hint at a centrifugal perspective whereby HHS and CMS reserve for themselves the greatest amount of discretion in the greatest number of cases. There are some early indications that CMS is opting for rules that will add to its already significant burden instead of harnessing the incentives provided for private litigants.

Take the example of the self-referral disclosure protocol that was required for the Stark Law. This protocol governs the types of arrangements physicians can maintain with health care providers in which they have a financial interest.⁶⁹ Section 6409 of the Affordable Care Act requires the Secretary of HHS, in cooperation with the HHS Office of the Inspector General to establish a Medicare self-referral disclosure protocol (“SRDP”) for providers of services and suppliers to self-disclose actual or potential violations of the Stark Law.⁷⁰ Section 6409 requires the Secretary of HHS to inform providers of services and suppliers of how to disclose an actual or potential violation pursuant to the protocol through publication on the CMS website.⁷¹ Section 6409 also mandates that the SRDP must include direction to health care providers of services and suppliers on the specific person, official, or office to whom such disclosures shall be made and instruction on the implication of the SRDP on corporate integrity agreements and corporate compliance agreements.⁷² Section 6409(b) grants the Secretary of HHS the authority to reduce the amounts due for all violations of the Stark Law.⁷³ In establishing the amount by which an overpayment resulting from an actual or potential violation(s) may be reduced, the Secretary may consider: the nature and extent of the improper or illegal practice; the timeliness of such disclosure; the cooperation in providing additional information related to the disclosure; and such other factors as the Secretary considers

⁶⁸ Barbara Vandegrift, *Warning: Report and Return Overpayments in 60 Days or Risk False Claims Act*, HEALTHCARE FINANCE NEWS, June 1, 2010, available at <http://www.healthcarefinancenews.com/blog/warning-report-and-return-overpayments-60-days-or-risk-false-claims-act>.

⁶⁹ See 42 U.S.C. §1393nn.

⁷⁰ CENTERS FOR MEDICARE AND MEDICAID SERVICES, CMS VOLUNTARY SELF-REFERRAL DISCLOSURE PROTOCOL, http://www.cms.gov/PhysicianSelfReferral/Downloads/6409_SRDP_Protocol.pdf.

⁷¹ *Id.*

⁷² *Id.*

⁷³ CENTERS FOR MEDICARE AND MEDICAID SERVICES, CMS VOLUNTARY SELF-REFERRAL DISCLOSURE PROTOCOL, http://www.cms.gov/PhysicianSelfReferral/Downloads/6409_SRDP_Protocol.pdf.

appropriate.⁷⁴ Pursuant to the statute, the CMS-proposed SDRP allows providers to send an email disclosing an actual or potential violation which would suspend the 60 day period otherwise given to the provider to return overpayments.⁷⁵ CMS will subsequently investigate the disclosure. While the protocol requires providers to report in “good faith,” the upshot is to permit providers to escape private enforcement against overpayments by turning to overstretched regulators to determine (1) whether they, in fact, reported in good faith and (2) to assess for themselves the culpability of the provider.⁷⁶ While the Affordable Care Act grants the Secretary of HHS the authority to reduce the amounts owed under the Stark Law, there is no requirement that she do so and the force of Congressional enactments in FERA and the financial reform law counsels that she reduce overpayments only in limited circumstances. If the regulations are formed in that way, private actors will discover improper payments more readily and providers will act under a greater incentive to ensure that their contracts with physicians are lawful.

b. Suspending Overpayments for Credible Allegations of Fraud

Similarly, in its proposed rule implementing the Affordable Care Act’s provisions which suspend payments under Medicare and Medicaid for credible allegations of fraud, CMS proposes that it review “all allegations, facts, and information carefully and act judiciously on a case-by-case basis when contemplating a payment suspension, mindful of the impact that payment suspension may have upon a provider.”⁷⁷ CMS further proposes to provide four exceptions for suspension.⁷⁸ These exceptions would include an exception for “a determination by CMS that a payment suspension is not in the best interests of the Medicare program.”⁷⁹ The net effect of these proposals appears to be further centralization of both rulemaking and enforcement in the hands of CMS. As it concedes and the GAO confirms, the CMS is overburdened with existing command-and-control and performance standards-based regulatory structures.

2. Coordinating Existing Manuals and Payments Practices to Facilitate Incentive-Based Regulation

Furthermore, CMS should review its existing manuals, guidance and protocols to ensure that they are consistent with RAC bill auditing practices and that they do not hinder FCA claims. As with shaping rules from the perspective of private litigants, incentive-based regulation is facilitated by clearly defining payment practices and ensuring that processors comply with stated policies. Inconsistencies between regulations and payment manuals have frequently led courts to require reimbursements regarded as improper by CMS.⁸⁰ Recovery Audit Contractors’ efforts to recoup overpayments have been thwarted where Medicare Appeals Councils find that CMS manuals

⁷⁴ The provider cannot simultaneously request an advisory opinion from HHS. https://www.cms.gov/PhysicianSelfReferral/95_advisory_opinions.asp#TopOfPage.

⁷⁵ CENTERS FOR MEDICARE AND MEDICAID SERVICES, CMS VOLUNTARY SELF-REFERRAL DISCLOSURE PROTOCOL, http://www.cms.gov/PhysicianSelfReferral/Downloads/6409_SRDP_Protocol.pdf.

⁷⁶ *Id.*

⁷⁷ 75 Fed. Reg. 184 p. 58222.

⁷⁸ *Id.* at 58223.

⁷⁹ *Id.* In the case of a State agency determination for Medicaid, the exception would be a State agency’s determination that it was not in the interest of the Medicaid program.

⁸⁰ See e.g. *Maximum Home Health Care Inv. v. Shalala*, 272 F.3d 318 (6th Cir. 2001); *National Medical Enterprises v. Bowen*, 851 F.2d 291 (9th Cir. 1988); U.S. DEP’T OF HEALTH AND HUMAN SERVICES, OFFICE OF INSPECTOR GENERAL, CONSULTATIONS IN MEDICARE: CODING AND REIMBURSEMENT, available at <http://oig.hhs.gov/oei/reports/oei-09-02-00030.pdf>.

contained inconsistent language as to the validity of a claim.⁸¹ Conversely, private litigants, and, for that matter, the Department of Justice, are thwarted where payments appear to be improper under regulations or payment manuals, but CMS informally deems the payment valid and pays as a matter of course.⁸²

VI. Conclusion

This Article might be misconstrued as a targeted criticism of the Centers for Medicare and Medicaid Services, but that is not its aim. CMS administers a massive health insurance scheme more efficiently than its private-sector counterparts.⁸³ Moreover, implementation of the Affordable Care Act will require coordinated activity of agencies housed within the Department of Labor, the Department of the Treasury, the Department of Agriculture and others for which this argument is equally applicable. Agencies administering statutory schemes that involve government payments should be attuned to Congress's clear intent to mobilize private citizens who have information showing that the taxpayers are being duped or overcharged. While whistleblower law firms and the Department of Justice are able to participate in the comments-on-rulemaking process, ultimate action will be left in the hands of the agencies. Indeed, it is unlikely under any of the prevailing standards of review that their failure to consider relevant Congressional intent located in non-charging statutes would be subject to a court's scrutiny. Instead, rulemaking that facilitates private enforcement is justified ethically by the idea that Congress is the more democratic source of authority and practically by the fact that private litigants may ease agencies' already significant burden.

⁸¹ Order of Medicare Appeals Council in the case of O'Connor Hospital, *available at* <http://www.hhs.gov/dab/divisions/medicareoperations/macdecisions/oconnorhospital.pdf>.

⁸² *Shoes for Amputees? Medicare waste revealed*, ASSOCIATED PRESS (Sept. 23, 2008), *available at* <http://www.msnbc.msn.com/id/26860289>.

⁸³ The point is fiercely contested. On the raw numbers, Medicare appears to incur overhead expenses of about 4% while private sector insurers report overhead costs of about 12%. See *National Health Plan Could Save Billions in Paperwork: Study*, CONSUMERAFFAIRS.COM (Jan. 14, 2004), *available at* http://www.consumeraffairs.com/news04/health_plan.html#ixzz0iO90Khxd. Many argue that those numbers do not accurately capture the economic picture. Robert Book, Ph.D., *Medicare Administrative Costs Are Higher, Not Lower, Than for Private Insurance*, THE HERITAGE FOUNDATION (June 25, 2009), *available at* <http://www.heritage.org/research/reports/2009/06/medicare-administrative-costs-are-higher-not-lower-than-for-private-insurance>.