

University of Tennessee College of Law

Legal Scholarship Repository: A Service of the Joel A. Katz Law Library

UTK Law Faculty Publications

Faculty Work

4-2015

Breaking the Fever: A New Construct for Regulating Overtreatment

Isaac ("Zack") D. Buck

Follow this and additional works at: https://ir.law.utk.edu/utklaw_facpubs



Part of the [Law Commons](#)

Recommended Citation

Buck, Isaac ("Zack") D., "Breaking the Fever: A New Construct for Regulating Overtreatment" (2015). *UTK Law Faculty Publications*. 671.

https://ir.law.utk.edu/utklaw_facpubs/671

This Article is brought to you for free and open access by the Faculty Work at Legal Scholarship Repository: A Service of the Joel A. Katz Law Library. It has been accepted for inclusion in UTK Law Faculty Publications by an authorized administrator of Legal Scholarship Repository: A Service of the Joel A. Katz Law Library. For more information, please contact eliza.boles@utk.edu.



DATE DOWNLOADED: Wed Apr 6 08:39:22 2022

SOURCE: Content Downloaded from [HeinOnline](https://heinonline.org/HOL/License)

Citations:

Bluebook 21st ed.

Isaac D. Buck, Breaking the Fever: A New Construct for Regulating Overtreatment, 48 U.C.D. L. REV. 1261 (2015).

ALWD 7th ed.

Isaac D. Buck, Breaking the Fever: A New Construct for Regulating Overtreatment, 48 U.C.D. L. Rev. 1261 (2015).

APA 7th ed.

Buck, I. D. (2015). Breaking the fever: new construct for regulating overtreatment. U.C. Davis Law Review, 48(4), 1261-1318.

Chicago 17th ed.

Isaac D. Buck, "Breaking the Fever: A New Construct for Regulating Overtreatment," U.C. Davis Law Review 48, no. 4 (April 2015): 1261-1318

McGill Guide 9th ed.

Isaac D. Buck, "Breaking the Fever: A New Construct for Regulating Overtreatment" (2015) 48:4 UCD L Rev 1261.

AGLC 4th ed.

Isaac D. Buck, 'Breaking the Fever: A New Construct for Regulating Overtreatment' (2015) 48(4) U.C. Davis Law Review 1261

MLA 9th ed.

Buck, Isaac D. "Breaking the Fever: A New Construct for Regulating Overtreatment." U.C. Davis Law Review, vol. 48, no. 4, April 2015, pp. 1261-1318. HeinOnline.

OSCOLA 4th ed.

Isaac D. Buck, 'Breaking the Fever: A New Construct for Regulating Overtreatment' (2015) 48 UCD L Rev 1261

Provided by:

University of Tennessee College of Law Joel A. Katz Law Library

-- Your use of this HeinOnline PDF indicates your acceptance of HeinOnline's Terms and Conditions of the license agreement available at

<https://heinonline.org/HOL/License>

-- The search text of this PDF is generated from uncorrected OCR text.

-- To obtain permission to use this article beyond the scope of your license, please use:

[Copyright Information](#)

Breaking the Fever: A New Construct for Regulating Overtreatment

Isaac D. Buck*

The Department of Justice's ("DOJ") current theory of overtreatment regulation — and, in fact, all of the prominent amount of medical necessity-based health care fraud enforcement — adopts the argument that providers are violating the False Claims Act when they submit bills to the federal government for care they administered that is not medically necessary. Besides stoking the ire of the provider community, this regulatory strategy is susceptible to inefficiency, imprecision, and — as I have argued before — overuse. Whether a procedure was medically necessary can be a highly difficult question to answer, one easily swayed by clinically-complex details, and one made murkier by clinical and geographic variation, Medicare's often outdated and/or inaccurate coverage determinations, and overtreatment's settlement-based regulatory regime that features few trials. This strategy can stifle innovation and arrest the natural evolution of the standard of care.

Given these difficulties, and aware of the imminent cost challenges facing the Medicare program, this Article presents a proposal that seeks to improve the efficiency and intellectual honesty of overtreatment regulation by advocating for an explicit shift in the focus of enforcement from medical necessity to excess utilization. Instead of targeting providers and hospitals for a contravention of Medicare's medical necessity determination during a

* Copyright © 2015 Isaac D. Buck. Assistant Professor, Mercer University School of Law; Juris Doctor, University of Pennsylvania Law School; Master of Bioethics, University of Pennsylvania; Bachelor of Arts, Miami University (Ohio). I owe a debt of gratitude to the participants, readers, and organizers of the 2014 Works-In-Progress and New Scholars Panels at the Southeastern Association of Law Schools annual meeting and at the 2014 University of Kentucky Emerging Ideas Conference, where I presented earlier versions of this paper. Thanks especially to Jennifer Bard, Kathy Cerminara, Nicole Huberfeld, Joan Krause, and Thad Pope for their helpful comments on previous versions of this draft.

Thanks to Michelle, Audrey, and Lucy. As always, any errors or omissions are my own.

particular episode of care, this proposal submits that the DOJ would be better served to pursue providers who, over the course of a year, provide “too much” care when compared to similarly-situated peer providers. Using peer providers’ clinical behaviors as a comparative legal standard would clarify the harm that overtreatment regulation seeks to prevent, and relying on an accumulation of data would ensure that those who are pursued by the DOJ are those who are the most responsible for America’s overtreatment problem.

Besides freeing the DOJ’s attorneys from the thorny arguments that characterize medical necessity-based fraud cases, repositioning clinical expertise with providers, and deemphasizing Medicare’s unpredictable coverage determinations, this shift would allow the DOJ to take advantage of the regulatory bonus of “cascaded retreat,” where providers self-adjust their behavior to avoid investigation. Further, building on previous works, this construct would ensure the enforcement mechanism would avoid those comparatively innocuous cases in which innovators minimally diverge from a bureaucratic reimbursement or coverage standard. Most importantly, it would seek to finally provide a powerful incentive to American providers to “do less” without robbing doctors of their highly-valued autonomy or harming Medicare’s respectable quality of care. This would provide a long-awaited counterbalance to the considerable incentives that encourage providers to constantly provide more care in a time of fiscal cliffs and budget crises.

TABLE OF CONTENTS

INTRODUCTION	1263
I. A DEAD END: MEDICARE REIMBURSEMENT POLICY	1270
A. Costly Concerns	1271
B. “Reasonable and Necessary” and NCDs	1278
II. TAKING ADVANTAGE OF NEW TRANSPARENCY	1283
A. Waste in Plain Sight	1284
B. High Utilizers	1287
III. IN SEARCH OF A STANDARD	1289
A. Reimbursement Standards as Law	1290
B. Medical Necessity Regulation	1292
IV. A NEW CONSTRUCT OF OVERTREATMENT REGULATION	1297
A. Three Important Characteristics	1298
1. Cumulative Utilization	1298
2. Comparison with Similarly-Situated Peers	1300
3. Publicizing Utilization and Cost Data	1303
B. Regulatory Advantages	1303
1. Flexible Persuasion	1304

2. Increasing Accuracy	1306
3. “Cascaded Retreat”	1307
V. LEGAL AND PRACTICAL DEFENSIBILITY	1308
A. <i>Fraud-Based Legal Theories</i>	1310
1. A New Species of Worthless Services	1311
2. “Cost Plus” Fraud	1312
B. <i>Practical Details</i>	1315
1. Addressing Clinical Variation	1315
2. Focusing on the Big Utilizers	1317
CONCLUSION	1317

INTRODUCTION

In 2011, it was John Dempsey Hospital (“Dempsey”), a 174-bed¹ component of the University of Connecticut Health Center, that was in the news for allegedly administering computerized tomography (“CT”) scans at a rate well above the national average.² Specifically, physicians at Dempsey were allegedly administering chest “combination scans”³ — examinations that feature two different scans, the first without contrast and a second with contrast to “help make parts of the body stand out more clearly”⁴ — at nearly *ten times* the national average.⁵ And for patients with abdominal afflictions, 72% of patients allegedly received these double combination scans at Dempsey — easily outpacing the national average of 19%.⁶

¹ *University of Connecticut Health Center — John Dempsey Hospital*, U.S. NEWS & WORLD REPORT, <http://health.usnews.com/best-hospitals/area/ct/university-of-connecticut-health-center-john-dempsey-hospital-6160215> (last visited Aug. 3, 2014); see also *About Us*, UCONN HEALTH, <http://www.uchc.edu/about/index.html> (last modified Dec. 8, 2011).

² See Lisa Chedekel, *UConn’s Dempsey Hospital off the Charts in Controversial “Double CT Scan” Use*, CONN. HEALTH I-TEAM (Jan. 28, 2011), http://c-hit.org/2011/01/28/uconn_dempsey_hospital_off_the_charts/ [hereinafter *Hospital off the Charts*]; see also Julie Appleby & Jordan Rau, *Many Hospitals Overuse Double CT Scans, Data Show*, WASH. POST (June 18, 2011), http://www.washingtonpost.com/national/health-science/many-hospitals-overuse-double-ct-scans-data-shows/2011/06/16/AGvpTAaH_story.html.

³ See “Combination” or “Double” CT Scans of the Chest, NW. MED., <http://www.nmh.org/nm/quality-combination-double-ct-scan-of-chest> (last visited Aug. 3, 2014) (noting that “[c]ontrast shouldn’t be used if it is not needed. Most of the time, radiologists can get a good picture of the chest by just taking a CT scan without contrast”).

⁴ Chedekel, *Hospital off the Charts*, *supra* note 2.

⁵ *Id.* The 2011 report noted that, for patients who presented to Dempsey in need of chest CT scans, 48% received combination scans in 2008; the national average for chest combination CT scans was 5%. *Id.*

⁶ See *id.*

Unlike some other instances of overtreatment, excess combination scans can subject the patient to clearly identifiable harm; in addition to the extra cost to payers and patients for the added scan, administering combination scans exposes patients to large doses of radiation.⁷ Clinically, there are few legitimate reasons to perform a combination scan.⁸ Health experts have noted that providers “without radiologists on staff may be doing the double scans just to make sure they get a full package of information before sending a patient home,”⁹ but the Centers for Medicare and Medicaid Services (“CMS”) has flatly noted that combination scans for the chest are “usually not appropriate.”¹⁰

What makes an excess combination scan rate legally relevant is the fact that hospitals administering combination scans earn more in reimbursement from the Medicare program¹¹ than those that administer just one CT scan to a patient. When a provider or entity administers health care services that are not medically necessary, the care *may* implicate health care fraud and abuse laws. With no other administrative regulations that speak to the amount of combination scans that are appropriate — indeed, “Medicare doesn’t restrict the use of double scans or penalize those who perform lots of them”¹² — the regulation of excess health care is an “all or nothing” proposition. Excessive care is either legitimate or fraudulent; *excess*, by itself, does not seem to be deliberately regulated by any calibrated legal or administrative approach.¹³

⁷ See “Combination” or “Double” CT Scans of the Chest, *supra* note 3. Indeed, radiation exposure from a combination scan is “700 times higher than for a simple chest x-ray,” and for abdominal tests, “the radiation dose is comparable to that of approximately 400 chest x-rays.” Chedekel, *Hospital off the Charts*, *supra* note 2. Notably, one CT scan has been shown to “triple the risk of later developing brain cancer or leukemia.” Jane E. Brody, *Personal Health: Medical Radiation Soars, with Risks Often Overlooked*, N.Y. TIMES WELL BLOG, (Aug. 21, 2012, 4:02 PM), <http://well.blogs.nytimes.com/2012/08/20/medical-radiation-soars-with-risks-often-overlooked/>.

⁸ See Appleby & Rau, *supra* note 2; see also D.J. Brenner, *Minimising Medically Unwarranted Computed Tomography Scans*, 41 ANNALS OF THE ICRP, nos. 3–4, 2012 at 161, 162 (noting that double CT scans double the dose of radiation administered to the patient “without any concomitant increase in the information accrued”).

⁹ *Id.*

¹⁰ See Chedekel, *Hospital off the Charts*, *supra* note 2.

¹¹ See Appleby & Rau, *supra* note 2.

¹² *Id.*

¹³ The application of American fraud and abuse laws available to federal prosecutors, and penalties imposed, hinge on the intent of the actor, not harm to the public fisc. See, e.g., *United States v. Lorenzo*, 768 F. Supp. 1127, 1131, 1133 (E.D. Pa.

Dempsey became aware of its excess rate of combination scans after an internal review was completed in 2010;¹⁴ by the spring of 2013, the hospital “reduced the rate of double scans of the chest to below one percent”¹⁵ from its nearly 50% rate after a “concerted effort” through education and new training.¹⁶ The chair of radiology, Dr. Douglas Fellows, when discussing the excessive rate of combination scans in 2008, noted that “[i]t [was]n’t that they [physicians and emergency room personnel] were doing anything for the wrong reasons — it’s just that they were trained years ago.”¹⁷ No health care fraud action followed the excessive combination scan rate, and where billed, Medicare paid for each of the combination scans that Dempsey administered; in an era of aggressive enforcement of health care fraud,¹⁸ by escaping a federal fraud investigation, Dempsey was one of the lucky ones.

The Dempsey story is one illustrative example of the modern challenge of overtreatment in American health care. As a class, American providers and hospitals — generally incentivized to provide more care — administer too much care, and compounding the problem, too much of that care is too expensive.¹⁹ As a result, taxpayers and patients spend much more money on health care than citizens of any other country in the world.²⁰ With the United States

1991) (regarding a False Claims Act penalty that totaled more than \$18 million for a dentist who defrauded the government for \$130,719).

¹⁴ See Chedekel, *Hospital off the Charts*, *supra* note 2. Dempsey’s safety rating for a 2013 Consumer Reports issue was affected by its combination scan rate. See William Weir, *John Dempsey Hospital Ranks Last in Consumer Reports List, Says Information Outdated*, HARTFORD COURANT (Mar. 28, 2013), http://articles.courant.com/2013-03-28/health/hc-dempsey-ranking-20130327_1_consumer-reports-list-hospital-compare-hospital-consumer-assessment.

¹⁵ Lisa Chedekel, *Dempsey Hospital Makes Progress Reducing Double CT Scans*, CTWATCHDOG.COM (Apr. 4, 2013), <http://ctwatchdog.com/health/dempsey-hospital-makes-progress-reducing-double-ct-scans>.

¹⁶ See *id.*

¹⁷ *Id.*

¹⁸ The number of health care fraud investigations has increased in recent years. See Press Release, U.S. Dep’t of Health & Human Servs., Departments of Justice and Health and Human Services Announce Record-Breaking Recoveries Resulting from Joint Efforts to Combat Health Care Fraud (Feb. 26, 2014), *available at* <http://www.hhs.gov/news/press/2014pres/02/20140226a.html> (noting the numerous records that were set in health care fraud prosecutions in 2013).

¹⁹ See generally ORG. FOR ECON. CO-OPERATION & DEV., *WHY IS HEALTH SPENDING IN THE UNITED STATES SO HIGH?* (2011), *available at* <http://www.oecd.org/unitedstates/49084355.pdf> (reporting statistics that suggest that health spending is “much higher” than other OECD countries).

²⁰ See *id.* at 1.

spending one of every six dollars of its gross domestic product (“GDP”) on health care,²¹ and Medicare facing a ballooning number of beneficiaries,²² attorneys at the Department of Justice (“DOJ”) have scrambled to employ their anti-fraud tools in an effort to return money back to Medicare’s trust fund. As a consequence, stories like Dempsey’s often end with a fraud settlement.²³

But the DOJ’s haphazard efforts have lacked thoughtfulness and calibration. Besides possibly stifling innovation, potentially slowing the development of the standard of care,²⁴ and building a regulatory regime susceptible to overenforcement,²⁵ the DOJ has lacked a cohesive and coherent construct for regulating and penalizing overtreatment. As I have previously argued, by using the False Claims Act (“FCA”) as its chief tool for the regulation of overtreatment, the DOJ has relied on a blunt tool for a multifaceted challenge; it has created a regulatory regime with little stratification of wrongdoing, resulting in cascading settlements lacking in precedent and order.²⁶ This regulatory structure is unlikely to change, particularly entrenched due to: (1) the lack of political will to either amend the FCA or otherwise cabin it to prevent or limit it from widely applying to health care fraud; (2) Congress’ general ambivalence toward doing anything that may be characterized as being “soft” on fraud or crime; and (3) perhaps the most important reason, the undeniably lucrative

²¹ See Shirley S. Wang, *U.S. Health Spending: One of These Things Not Like Others*, WALL ST. J. ECON. BLOG (Jul. 23, 2013, 2:05 PM), <http://blogs.wsj.com/economics/2013/07/23/u-s-health-spending-one-of-these-things-not-like-others/>.

²² The major challenge for Medicare’s future cost is a result of its upcoming population explosion, with the aging of the Baby Boomer generation. See generally CTRS. FOR DISEASE CONTROL & PREVENTION, *THE STATE OF AGING AND HEALTH IN AMERICA 2013*, at ii (2013), available at http://www.cdc.gov/features/agingandhealth/state_of_aging_and_health_in_america_2013.pdf (“The growth in the number and proportion of older adults is unprecedented in the history of the United States. Two factors — longer life spans and aging baby boomers — will combine to double the population of Americans aged 65 or older during the next 25 years to about 72 million. By 2030, older adults will account for roughly 20% of the U.S. population.”).

²³ See generally Isaac D. Buck, *Caring Too Much: Misapplying the False Claims Act to Target Overtreatment*, 74 OHIO ST. L.J. 463 (2013) [hereinafter *Caring Too Much*] (recounting many instances of the DOJ’s zealous pursuit of settlements in medical fraud cases).

²⁴ See *id.* at 499-501.

²⁵ See Isaac D. Buck, *Enforcement Overdose: Health Care Fraud Regulation in an Era of Overcriminalization and Overtreatment*, 74 MD. L. REV. 259, 263-64 (2015) [hereinafter *Enforcement Overdose*].

²⁶ See Buck, *Caring Too Much*, *supra* note 23, at 469.

return on investment of health care fraud enforcement for the federal government.²⁷

Granted, the solution to this challenge *could be* an administrative one — that is, CMS and Health and Human Services (“HHS”) could establish a mechanism by which they fine providers or entities that are “overutilizers.”²⁸ CMS could have automatically imposed a fine on Dempsey, for instance, for exceeding an acceptable range of combination CT scans. Indeed, Medicare itself could simply refuse to pay for care that is excessive; reimbursement policy could take a more intentional and constricting tack, but — for many of the same structural reasons — Medicare remains unlikely to do so. It makes intuitive sense to elect a softer, more granular tool than the FCA to prevent overtreatment, but such a shift seems doubtful. As a result, the primary challenge presented by regulating overtreatment is in building an orderly framework within this larger environment of disorder.

Within this environment, the “second-best” solution may be to recalibrate and retarget the investigation of overtreatment to improve its consistency and accuracy. Indeed, a gap exists between current overtreatment *legal theory* — which almost completely relies upon the allegation that care at issue was not medically necessary — and the *reality* of the overtreatment problem — which is characterized by cumulative overutilization, for one reason or another.²⁹ Indeed, at

²⁷ See Buck, *Enforcement Overdose*, *supra* note 25, at 263-64.

²⁸ Indeed, section 3025 of the Patient Protection and Affordable Care Act (“ACA”) penalizes hospitals for readmission rates. See Patient Protection and Affordable Care Act of 2010, Pub. L. No. 111-148, § 3025, 124 Stat. 119, 408-13 (2010) (codified as amended at 42 U.S.C. § 1395ww (2012)); *Readmissions Reduction Program*, CTRS. FOR MEDICARE & MEDICAID SERVS., <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Readmissions-Reduction-Program.html> (last modified Aug. 4, 2014). In 2014, 2,225 hospitals were penalized. CMS: *The 2,225 Hospitals That Will Pay Readmissions Penalties Next Year*, DAILY BRIEFING (Aug. 5, 2013), <http://www.advisory.com/daily-briefing/2013/08/05/cms-2225-hospitals-will-pay-readmissions-penalties-next-year>. Nevertheless, there are no specific provisions in the ACA that seek to control or limit the overall amount of health care services within the doctor-patient relationship.

²⁹ Overtreatment cases center on the medical necessity of a procedure, often to the confusion of the targeted provider. See, e.g., Lisa Schencker, *Dignity Health Pays \$37 Million in False-Claims Action*, MODERN HEALTHCARE (Oct. 30, 2014), <http://www.modernhealthcare.com/article/20141030/NEWS/310309940> (noting a settlement entered into by Dignity Health for improper and medically unnecessary hospital admissions, with Dignity noting that the “billing disputes” at issue “reflect widespread confusion in the health care industry on unclear federal standards for approving coverage of patient admissions”). However, the challenge of overtreatment itself is a much broader issue, especially if up to 30% of health care in the United States is spent on wasted services. See Editorial, *Waste in the Health Care System*, N.Y. TIMES (Sept. 10, 2012), <http://www.nytimes.com/2012/09/11/opinion/waste-in-the-health-care->

Dempsey, the harm was not that *certain* combination CTs were not medically necessary, but instead, the harm was Dempsey's cumulative excessive administration of combination CTs. It is the *excess*, not the demonstrated *lack of necessity*, which harms the Medicare program and should be the chief target of overtreatment regulation.

This piece advocates for a regulatory change by presenting a new, but seemingly simple, construct of overtreatment regulation. Specifically, this piece recommends that the DOJ reconceive of overtreatment regulation — from the targets of its investigations to the legal arguments it espouses — as primarily pursuing providers responsible not for *unnecessary care* based on some government-established medical necessity standard, but instead, targeting those providers responsible for *excessive cumulative utilization* compared to other, similarly-situated peer providers. Indeed, the challenge in reigning in government spending in the Medicare program has less to do with preventing the filing of *per se* false claims with the government, and more to do with reordering incentives so participating providers limit volume and cost.³⁰ Medicare has been unable to slow cost growth due to a complex relationship with cost control and its strong protection of clinical autonomy. As a result, an opening has appeared for the DOJ to use its regulatory tools — albeit in a more transparent, calibrated, and perhaps limited way than in the past — to explicitly limit rising expense by targeting the excess utilization of health services. Such a shift would not only allow the DOJ to reach situations like those posed by the Dempsey Hospital discussion, but would force overtreatment regulation into a much needed new era.

A number of advantages come with this nuanced shift. First, reconceiving of the harm from *unnecessary care* to *excessive utilization* frees regulators from the thorny arguments surrounding clinical practice, scientific advances, and patient harm. Instead, they can focus on the true threat of overtreatment — overutilization, and, relatedly, excess cost.³¹ DOJ attorneys would no longer have to dwell in artery occlusion percentages or qualify the severity of an adverse cardiac

system.html; Delos Cosgrove et al., A CEO Checklist for High-Value Health Care 4 (June 5, 2012) (unpublished manuscript), <http://www.iom.edu/~media/Files/Perspectives-Files/2012/Discussion-Papers/CEOHIGHValueChecklist.pdf>.

³⁰ See Ezekiel J. Emanuel & Victor R. Fuchs, *The Perfect Storm of Overutilization*, 299 J. AM. MED. ASS'N 2789, 2790 (2008).

³¹ See Tara Parker-Pope, *Overtreatment is Taking a Harmful Toll*, N.Y. TIMES WELL BLOG (Aug. 27, 2012, 2:37 PM), <http://well.blogs.nytimes.com/2012/08/27/overtreatment-is-taking-a-harmful-toll/> (documenting instances of wasteful, costly care).

event; instead, utilization rates per patient would drive the analysis. Second, and relatedly, this shift would give regulators a well-defined and quantifiable measure with which to discern harm to the federal health care programs, always granting them a defensible focus of investigation. Third, by setting peer-based comparison as the basis for liability, the enforcement framework would reposition clinical control back within the medical community, ending the clashes between government regulators and clinicians over the worthwhileness of a particular medical procedure — a battle, which for various reasons, produces few real winners. Those providers who come under the DOJ's microscope would be those who are the most out of step with their peers, not those most out of step with Medicare's medical necessity standard. Most importantly perhaps, breaking from decades of legal incentives for providers to do *more*, this new conception of overtreatment regulation clearly incentivizes providers to do *less* without robbing them of their highly valued autonomy. Maintaining this autonomy but encouraging less care seeks to both slow spiraling cost and maintain the quality of care administered to Medicare's nearly fifty million beneficiaries.³²

In order to fully detail the proposal, this analysis will proceed in five parts. Part I explores structural characteristics that impact Medicare's ability to control costs — limiting its ability to provide a satisfactory regulatory answer to overtreatment.³³ Part II presents evidence demonstrating the dawn of a new data-driven and transparent era regarding costs in Medicare.³⁴ Part III summarizes overtreatment investigations with different postures in an effort to make clear key considerations in fraud and abuse regulation today.³⁵ Part IV presents the solution of encouraging government prosecutors to focus on providers engaged in excess utilization and summarizes practical advantages.³⁶ Finally, Part V presents a legal and policy-based defense of the new regime, as health care fraud enforcement seeks solutions to Medicare's seemingly intractable cost crisis.³⁷

³² See *Total Number of Medicare Beneficiaries, 2012*, KAISER FAMILY FOUND., <http://kff.org/medicare/state-indicator/total-medicare-beneficiaries/> (last visited June 26, 2014).

³³ See *infra* Part I.

³⁴ See *infra* Part II.

³⁵ See *infra* Part III.

³⁶ See *infra* Part IV.

³⁷ See *infra* Part V.

I. A DEAD END: MEDICARE REIMBURSEMENT POLICY

Medicare, by and through its administrators at CMS, plays a major role in clinical standard-setting within American medicine. By its medical necessity determinations and more formal national coverage determination (“NCD”) and, where relevant, local coverage determination (“LCD”) processes, Medicare and its contractors set clinical standards for participating providers by establishing reimbursement policy.³⁸ These determinations go beyond the boundaries of Medicare; in addition to setting reimbursement for the program, Medicare’s coverage determinations influence private insurers.³⁹ Indeed, the program’s “reimbursement and coverage policies have been widely adopted by private insurers and other public programs,” and “many private insurers follow Medicare’s lead in approving coverage of new medical technologies,”⁴⁰ making it the “country’s preeminent organization for the assessment of health technology.”⁴¹

This standard-setting function, while powerful, is far from perfect, and is impacted by two types of structural complexities within the program. These structural complexities have hampered Medicare’s ability to control costs. And both dilute the accuracy and potency of Medicare’s standards.

First, Medicare’s ability to set accurate clinical standards is impacted by its complicated relationship and history with cost control. Most basically, statutory and historical restraints on the Medicare program prevent it from fully taking cost into account when determining

³⁸ See Michael J. DeBoer, *Medicare Coverage Policy and Decision Making, Preventive Services, and Comparative Effectiveness Research Before and After the Affordable Care Act*, 7 J. HEALTH & BIOMEDICAL L. 493, 520-31 (2012) (documenting the coverage process, including the role of the Medicare Evidence Development and Coverage Advisory Committee).

³⁹ See Jacqueline Fox, *The Hidden Role of Cost: Medicare Decisions, Transparency and Public Trust*, 79 U. CIN. L. REV. 1, 15 (2010) [hereinafter *The Hidden Role of Cost*].

⁴⁰ PAUL N. VAN DE WATER, CTR. ON BUDGET & POL’Y PRIORITIES, MEDICARE CHANGES CAN COMPLEMENT HEALTH REFORM 3 (2008), available at <http://www.cbpp.org/files/7-31-08health.pdf>; see Gillian Mohnney, *Eye Lifts — Fine Line Between Cosmetic and Therapeutic*, ABC NEWS (May 31, 2013, 6:00 AM), <http://abcnews.go.com/blogs/health/2013/05/31/eye-lifts-fine-line-between-cosmetic-and-therapeutic/> (noting how other insurance companies follow Medicare’s lead on determining whether a procedure is medically necessary or not).

⁴¹ Peter J. Neumann & James D. Chambers, *Medicare’s Enduring Struggle to Define “Reasonable and Necessary” Care*, 367 NEW ENG. J. MED. 1775, 1775 (2012) (“Its decisions to cover and pay for medical technology can have profound consequences for patients’ access to therapies, physicians’ treatment options, and the fiscal well-being of the program.”).

whether to cover a new procedure for its beneficiaries, ultimately producing, as Professor Jacqueline Fox has noted, “distorted” coverage results.⁴² In this way, Medicare differs from private payers; where private payers can substantially impact clinical practice by their refusal to pay for non-medically-necessary procedures,⁴³ or by limiting their networks, Medicare has few levers within its reimbursement scheme that it can engage to dissuade providers from administering overtreatment.

Second, beyond the awkward cost issue within Medicare generally, its own formal NCD and LCD process is influenced by a bias toward providing coverage for new and expensive technologies and services. The standard-setting process-based constraints pressure Medicare into covering more procedures and products, both in number and price, which undoubtedly affects its ability to slow rising costs within the program. As a result, the coverage standard itself — even when enforced — may not be reflective of the most accurate and deliberative process. Both of these phenomena are presented below.

A. Costly Concerns

When it comes to cost control, and as so aptly presented by Professor Nicolas Bagley,⁴⁴ for all of its success, America’s seminal public insurance program of Medicare suffers from chronic and critical design flaws. As many Americans know, the program is politically popular⁴⁵ but financially troubled,⁴⁶ particularly because it has so

⁴² See Nicholas Bagley, *Bedside Bureaucrats: Why Medicare Reform Hasn’t Worked*, 101 GEO. L. REV. 519, 549-50 (2013) (providing a historical analysis of Medicare’s cost challenges); Fox, *The Hidden Role of Cost*, *supra* note 39, at 15.

⁴³ See Linda A. Bergthold, *Medical Necessity: Do We Need It?*, 14 HEALTH AFF. 180, 181-83 (1995) (“Medical necessity has become a major tool for allocating health care resources in a time of increasing costs.”); see, e.g., *Medical Necessity*, ILL. DEP’T. OF INS., http://insurance.illinois.gov/HealthInsurance/Medical_Necessity.asp (last visited Aug. 11, 2014) (“Insurance companies and HMOs exclude coverage for treatment that is not medically necessary because they do not want to extend benefits for unnecessary treatment or for care that might be potentially dangerous or harmful to their members.”).

⁴⁴ See Bagley, *supra* note 42, at 541-44.

⁴⁵ Cf. *Seniors Most Likely to Say Medicare Is Working Well*, KAISER FAMILY FOUND. (Mar. 12, 2013), <http://kff.org/medicare/slide/seniors-most-likely-to-say-medicare-is-working-well/> (noting that 80% of individuals aged sixty-five or over responded to a recent poll that “Medicare is working well,” compared to just 60% of all Americans).

⁴⁶ Cf. *Projected Medicare Spending, 2013–2023*, KAISER FAMILY FOUND. (July 15, 2013), <http://kff.org/medicare/slide/projected-medicare-spending-2013-2023/> (noting that Medicare spending is projected to increase 182% between 2013 and 2023).

limited its ability to control costs.⁴⁷ As currently constituted, it has largely left the implementation of various cost control up efforts to the participating providers “at the bedside,”⁴⁸ apparently expecting physicians to act directly against their own financial interests.⁴⁹

For nearly fifty years, Medicare has ceded much of its cost-constraining power to the medical profession, and as a result, throughout Medicare’s existence, providers have enjoyed largely-unchallenged autonomy through fee-for-service reimbursement with little incentive to rein in costs.⁵⁰ Waves of cost control efforts have proven unsuccessful, often due to political motives.⁵¹ Today, Medicare resembles a public option insurance plan for the elderly, but has imposed few restrictions on the physicians who treat its beneficiaries.⁵² And as a bulk purchaser of health care services, Medicare has failed to use much of its considerable leverage⁵³ to hold down the price of doctor visits, pharmaceutical drugs,⁵⁴ or surgeries.⁵⁵

⁴⁷ See Bagley, *supra* note 42, at 527 (“Structuring Medicare as an entitlement to indemnification keyed to judgments of medical necessity meant that Congress surrendered direct control over the size of Medicare funding.”).

⁴⁸ *Id.* at 521 (noting that physicians have remained in control of the program throughout its existence).

⁴⁹ See *id.* at 543 (“Medical societies have not assumed the wished-for leadership role in promoting cost-conscious care, and why would they? They’re trade associations, not regulators.”).

⁵⁰ See David A. Hyman, *Health Care Fraud and Abuse: Market Change, Social Norms, and the Trust “Reposed in the Workmen,”* 30 J. LEGAL STUD. 531, 537 (2001) (“Providers decided which services were required, where they would be delivered, and how much they would cost. . . . Medicare exercised little or no oversight over the services that were provided, the amounts that were billed, and the quality of the medical care that was delivered.”); Eleanor Kinney, *Medicare Coverage Decision-Making and Appeal Procedures: Can Process Meet the Challenge of New Medical Technology?*, 60 WASH. & LEE L. REV. 1461, 1466 (2003) (noting that “the designers deliberately maintained the fee-for-service payment methods for all providers, thereby seeding cost inflation, to ensure the participation of reluctant providers”).

⁵¹ See, e.g., Virgil Dickson, *CMS Backs Off Major Changes to Medicare Part D*, MODERN HEALTHCARE (Mar. 10, 2014), <http://www.modernhealthcare.com/article/20140310/NEWS/303109971> (documenting that the Obama administration “backed away from major changes” that was “intended to control costs”).

⁵² See Bagley, *supra* note 42, at 521, 527. Different from public option plans, which limit costs because of bargaining power and sheer size, Medicare does not take cost into account.

⁵³ See Bagley, *supra* note 42, at 551 (noting that Medicare does not negotiate price terms and also noting that Medicare fails to “reliably enforce NCDs”); see also *id.* at 567 (“Unsurprisingly, Medicare has spawned an enormous amount of fraud and abuse. . . . Congress . . . has consistently declined to give CMS the resources it would need to do its job well.”).

⁵⁴ An example of a congressional action that has contributed to the spiraling cost

Unsurprisingly, these design flaws make Medicare particularly susceptible to generating a large cumulative amount of unnecessary care, which in turn, places its long-term financial sustainability in question. As Professor Eleanor Kinney has noted:

[Since the inception of the program,] the structure and financing of Medicare and private health insurance plans [have] contributed to excessive utilization of health care services. . . . [B]eneficiaries [have been] insulated from the financial consequences of their decisions to use health care services and provider payment methods [have been] based on incurred costs and charges which encouraged inefficiencies in care delivery.⁵⁶

It is Congress that has created this situation for Medicare, largely — perhaps ironically — by historical design.⁵⁷ Not wanting to scare

problem within Medicare is the imposition of a limit on Medicare that prevents it from being able to negotiate prices with drug companies. This prohibition has been in place since the passage of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, and largely affects Medicare Part D — but also impacts physician services under Part B. See Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (codified as amended in scattered sections of 42 U.S.C.).

Throughout the last couple of years, the debate surrounding Medicare's ability to negotiate prices with drug companies has come in and out of the public consciousness. Some say "it could save billions of dollars annually." Editorial, *Medicare: A Plan B for Part D*, L.A. TIMES (Dec. 21, 2012), <http://articles.latimes.com/2012/dec/21/opinion/la-ed-medicare-prescription-drug-negotiated-prices-20121221>. Indeed, "simply giving Medicare's low-income beneficiaries the same discount under Medicaid would save \$116 billion over 10 years." Editorial, *Let Medicare Negotiate Drug Prices: Our View*, USA TODAY (Apr. 20, 2014, 5:50 PM EDT), <http://www.usatoday.com/story/opinion/2014/04/20/medicare-part-d-prescription-drug-prices-negotiate-editorials-debates/7943745/>.

⁵⁵ See Elisabeth Rosenthal, *Patients' Costs Skyrocket; Specialists' Incomes Soar*, N.Y. TIMES (Jan. 18, 2014), <http://www.nytimes.com/2014/01/19/health/patients-costs-skyrocket-specialists-incomes-soar.html> (presenting examples of surgery's costs that have grown wildly, and that "Medicare has not reduced payments for many procedures that now take far less time than when they were invented, because of improvements in efficiency or technology").

⁵⁶ Kinney, *supra* note 50, at 1467.

⁵⁷ See Bagley, *supra* note 42, at 553 ("The enacting Congress's painstaking efforts to avoid interfering in physician treatment decisions, Congress's refusal in the forty-eight years since to explicitly authorize the consideration of costs, and a deep societal distaste for government rationing all lend considerable force to the intuition that Congress has never authorized Medicare to consider cost in making coverage determinations."); see also DeBoer, *supra* note 38, at 512 (noting that "[t]hese payment methods helped to attract providers to the program, but they also contributed to overutilization of health care services, promoted provider inefficiencies,

doctors away from initially enrolling in the program, Medicare sweetened the deal for participating providers.⁵⁸ Participation in the program quickly proved quite lucrative for a number of providers, and cost inflation rapidly began in the early years of Medicare.⁵⁹ That inflation has continued — largely unabated and unresolved — for five decades.⁶⁰

Today, where it has attempted to fill gaps by providing day-to-day regulatory guidance, Congress has failed to provide agency resources to oversee enforcement of the regulations.⁶¹ Decades since its original construction, the costs⁶² of the growing⁶³ program have forced the federal government to consider radical changes to its structure.⁶⁴ And with the exploding number of new beneficiaries enrolling in the program over the next fifteen years,⁶⁵ Medicare's cost pressures will likely only intensify.⁶⁶ Debate surrounding how the program should

and produced dramatic increases in the prices and costs of health care").

⁵⁸ See Kinney, *supra* note 50, at 1466; see also Nancy-Ann DeParle, *Medicare at 40: A Mid-Life Crisis?*, 7 J. HEALTH CARE L. & POL'Y 70, 75-77 (2004) ("Medicare's creators worried that physicians would refuse to participate in the program, so they bent over backward to make it simple: physicians sent bills for their usual and customary fees to patients, and money flowed back from the government.").

⁵⁹ See Kinney, *supra* note 50, at 1467 ("Immediately upon implementation, the Medicare program generated enormous demand for health care services, and thus created sharp and continuing increases in the cost of health care."); see also DeParle, *supra* note 58, at 77.

⁶⁰ See Editorial, *Health Costs and History*, WALL ST. J. (Oct. 20, 2009), <http://online.wsj.com/news/articles/SB10001424052748703746604574461610985243066> (noting the cost growth and inaccuracy of early cost projections for Medicare).

⁶¹ See Bagley, *supra* note 42, at 529 ("Congress deprived federal administrators of the conventional roster of legal and management tools typically used to control frontline bureaucrats."); *id.* at 551 ("There is no indication that CMS evaluates its contractors on whether they enforce their coverage determinations — or that CMS would even have the resources to do so.").

⁶² Medicare cost American taxpayers \$586 billion in 2013, and is projected to cost more than \$1 trillion starting in 2022. See *Projected Medicare Spending, 2013–2023*, *supra* note 46.

⁶³ In 2013, about 52 million Americans were on Medicare. See *Medicare: The Essentials*, KAISER FAMILY FOUND., <http://kff.org/slideshow/medicare-the-essentials/> (last visited May 28, 2014).

⁶⁴ See, e.g., Steve Vernon, *The Ryan Medicare Plan: A Critical Look*, CBS NEWS (Aug. 31, 2012, 7:35 AM), <http://www.cbsnews.com/news/the-ryan-medicare-plan-a-critical-look/> (suggesting a voucher-based Medicare plan).

⁶⁵ By 2025, the number of beneficiaries enrolled in the Medicare program is projected to top 73 million Americans, and by 2035, more than 86 million Americans are projected to be in the program. See *Medicare Enrollment, 1970–2035*, KAISER FAMILY FOUND. (July 15, 2013), <http://kff.org/medicare/slide/medicare-enrollment-1970-2035/>.

⁶⁶ Cf. *Projected Medicare Spending, 2013–2023*, *supra* note 46 (forecasting that

change has exposed the conflicts that exist between individualism and utilitarianism, between taxpayers and patients, and between law and medicine.⁶⁷ On those counts up to this point, Medicare has chosen individuals, patients, and medicine⁶⁸ — but not without consequences.

The one inflection point where Medicare *could* seek to reverse rising expense is to explicitly consider cost when deciding which types of procedures and products it will cover. Much like health management organizations (“HMOs”) in the 1980s and early 1990s⁶⁹ and private insurance companies throughout modern America’s health care delivery system, Medicare could constrict the type and nature of services for which it reimburses. Less drastically, Medicare could pay only for procedures and services that are cost-effective, using its ability to set reimbursement rates to try and influence provider behavior.⁷⁰ As Professor Fox has noted, this would allow beneficiaries and citizens to engage in a robust debate about what types of procedures are worthwhile.⁷¹

But neither of these suggestions has been implemented. Indeed, unlike private insurance companies, due to statutory prohibition,⁷² Medicare cannot consider the cost-effectiveness of a procedure in

Medicare spending will exceed \$1 trillion per year by 2023).

⁶⁷ See Douglas Holtz-Eakin & Ken Thorpe, *The Current Medicare Debate Will Not Solve the Program’s Problems*, HEALTH AFFAIRS BLOG (Feb. 12, 2013), <http://healthaffairs.org/blog/2013/02/12/the-current-medicare-debate-will-not-solve-the-programs-problems/> (noting that changing Medicare requires “structural reforms”); David Jackson, *Obama-Romney-Ryan Medicare Debate Takes Surprising Turn*, USA TODAY (Aug. 19, 2012, 1:14 PM), <http://content.usatoday.com/communities/theoval/post/2012/08/obama-romney-medicare-debate-takes-a-turn/1#.VH4z9L64lO0> (referencing the conflict during the 2012 presidential election over the future of Medicare).

⁶⁸ See Bagley, *supra* note 42, at 533 (noting that Congress has “struck the balance decisively in favor of physician autonomy”).

⁶⁹ See Peter Passell, *Backlash; in Medicine, Government Rises Again*, N.Y. TIMES (Dec. 7, 1997), <http://www.nytimes.com/1997/12/07/weekinreview/backlash-in-medicine-government-rises-again.html>; see also Maxim L. Pinkovskiy, *The Impact of the Managed Care Backlash on Health Care Costs: Evidence from State Regulation of Managed Care Cost Containment Practices 1-2* (Oct. 17, 2013) (unpublished manuscript), available at <http://economics.mit.edu/files/8448>.

⁷⁰ See Fox, *The Hidden Role of Cost*, *supra* note 39, at 47-49 (suggesting that Medicare use cost in coverage determinations).

⁷¹ See *id.*

⁷² See 42 U.S.C. § 1395 (2012) (preventing federal interference in the practice of medicine); see also Jacqueline Fox, *Medicare Should, But Cannot, Consider Cost: Legal Impediments to a Sound Policy*, 53 BUFF. L. REV. 577, 584-95 (2005) [hereinafter *Medicare Should Consider Cost*] (providing historical and legal background to the prohibition on cost consideration).

making its coverage determinations.⁷³ Even though CMS's predecessor tried to explicitly consider cost in coverage determinations in the late 1980s,⁷⁴ CMS is still prevented from explicitly reviewing the cost-effectiveness of services. This is likely due to the historical and statutory structure of the program,⁷⁵ the deep distrust that comes with "too much" government regulation of health care,⁷⁶ and a concern that physicians will no longer participate in the program if not given nearly-complete autonomy,⁷⁷ leading to congressional acts that have repealed cost-cutting measures.⁷⁸

⁷³ See Bagley, *supra* note 42, at 526 ("Because physicians' prevailing conception of medical necessity was (and is) cost blind, eligibility for Medicare payments depended not at all on the costs of the treatment in question.").

⁷⁴ See Medicare Program; Criteria and Procedures for Making Medical Services Coverage Decisions That Relate to Health Care Technology, 54 Fed. Reg. 4302, 4303 (proposed Jan. 30, 1989) (to be codified at 42 C.F.R. pts. 400, 405) (noting that the Health Care Finance Administration, CMS's predecessor, tried to change its reimbursement formula to consider cost-effectiveness); see also Fox, *The Hidden Role of Cost*, *supra* note 39, at 19.

⁷⁵ See Fox, *The Hidden Role of Cost*, *supra* note 39, at 11-14.

⁷⁶ This distrust affected the debate and implementation of the ACA, characterized by President Obama's adversaries as a "government takeover of health care." See, e.g., DAVID GRATZER, WHY OBAMA'S GOVERNMENT TAKEOVER OF HEALTH CARE WILL BE A DISASTER (2009) (arguing that the Affordable Care Act would harm American health care); Emily Miller, Editorial, *Obamacare Is a Trojan Horse for Government-Run Health Care Starting in 2015*, WASH. TIMES (Mar. 19, 2014), <http://www.washingtontimes.com/news/2014/mar/19/miller-obamacare-a-trojan-horse-for-government-run/> ("Mr. Obama's objective has always been to entrench the doomed law into our lives so that it would lead to a government takeover of the whole health care system. This maniacal plan is working."); Avik Roy, *Government Takeover: White House Forces Obamacare Insurers to Cover Unpaid Patients at a Loss*, FORBES (Dec. 14, 2013, 7:42 AM), <http://www.forbes.com/sites/theapothecary/2013/12/14/government-takeover-white-house-forces-obamacare-insurers-to-cover-unpaid-patients-at-a-loss/> ("If Obamacare wasn't a government takeover of the health insurance industry, then what it is now?").

Echoing this concern, allegations of death panels, claims of socialized medicine, and calls to "keep your government hands off my Medicare" began shortly after debate began in 2009. See Timothy Noah, *The Medicare-Isn't-Government Meme*, SLATE (Aug. 5, 2009, 2:04 PM), http://www.slate.com/articles/news_and_politics/prescriptions/2009/08/the_medicareisntgovernment_meme.html; Philip Rucker, *Sen. DeMint of S.C. Is Voice of Opposition to Health-Care Reform*, WASH. POST (Jul. 28, 2009), http://www.washingtonpost.com/wp-dyn/content/article/2009/07/27/AR2009072703066_2.html. These reactions to the ACA highlighted deep-seated distrust of governmental involvement in health care, and largely steered the debate for the following five years, limiting the amount of realistic options for reform. See generally Helen A. Halpin & Peter Harbage, *The Origins and Demise of the Public Option*, 29 HEALTH AFF. 1117 (2010) (noting how the public option became a main point of controversy).

⁷⁷ See Bagley, *supra* note 42, at 557-58.

⁷⁸ See Wesley Lowery, *For 17th Time in 11 Years, Congress Delays Medicare Reimbursement Cuts as Senate Passes "Doc Fix"*, WASH. POST (Mar. 31, 2014),

Even though cost may be considered behind the scenes,⁷⁹ there is neither public debate surrounding, nor an explicit recognition that cost concerns impact, coverage determinations.⁸⁰ As Professor Fox has argued, determinations resulting from the “reasonable and necessary” language of the Medicare statute,⁸¹ to NCDs,⁸² to third-party coverage conclusions,⁸³ based upon medical necessity — that is, whether a treatment was reasonable and necessary for the health of a beneficiary — can be distorted.⁸⁴ Consequently, Medicare pays for expensive surgeries that have limited utility; recent research has concluded that “CMS is covering a number of interventions that do not appear to be cost-effective.”⁸⁵ Beyond failing to pay for only cost-effective care, Medicare has also come under fire for paying for a growing number of potentially cosmetic surgeries.⁸⁶

A growing chorus of scholars and clinicians has argued that CMS should, in fact, take cost into consideration when crafting medical necessity standards and coverage determinations.⁸⁷ However, Congress

<http://www.washingtonpost.com/blogs/post-politics/wp/2014/03/31/for-17th-time-in-11-years-congress-delays-medicare-reimbursement-cuts-as-senate-passes-doc-fix/>; see, e.g., Protecting Access to Medicare of 2014, H.R. 4302, 113th Cong. § 101 (2014) (updating the conversion factor to 0.0, thus undoing the sustainable growth rate formula for another year).

⁷⁹ See Fox, *The Hidden Role of Cost*, *supra* note 39, at 5 (“CMS often flatly denies that cost impacts its specific decisions, yet its management continually stresses the importance of cost control. As a result of these conflicting messages, and in light of CMS’s actual decisions, it has become an ‘open secret’ in health policy that CMS considers cost when issuing NCDs.”).

⁸⁰ *Id.*

⁸¹ 42 U.S.C.A. § 1395y (West 2014) (laying out exclusions from Medicare coverage).

⁸² See *Medicare Coverage Determination Process*, CTRS. FOR MEDICARE & MEDICAID SERVS., <http://www.cms.gov/Medicare/Coverage/DeterminationProcess/> (last modified Nov. 27, 2013).

⁸³ See DeBoer, *supra* note 38, at 506 (“In the absence of national coverage policy, regional or local Medicare administrative contractors make determinations of coverage as to items and services.”).

⁸⁴ See Fox, *The Hidden Role of Cost*, *supra* note 39, at 7 (arguing that the failure to consider cost in Medicare’s coverage determinations “distorts” the process).

⁸⁵ See James D. Chambers et al., *Does Medicare Have an Implicit Cost-Effectiveness Threshold?*, 30 MED. DECISION MAKING E14, E17 (2010).

⁸⁶ See Mohney, *supra* note 40 (noting the debate over whether Medicare should pay for blepharoplasties (eyelid lift surgeries), and that eyelid lifts covered by Medicare have experienced “a threefold increase since 2001,” but nationwide, the total number performed has dropped by 38%).

⁸⁷ See SEAN R. TUNIS ET AL., URBAN INST., IMPROVING THE QUALITY AND EFFICIENCY OF THE MEDICARE PROGRAM THROUGH COVERAGE POLICY 14 (2011), available at <http://healthreformgps.org/wp-content/uploads/Urban-Institute-Medicare-Coverage->

has not been motivated to change the process.⁸⁸ As a result, CMS is left in an awkward position — charged with stewardship over America's crown jewel public insurance program but with very little ability to prevent it from traversing a fiscal cliff. It has become a passenger in a runaway train without access to the brakes.

B. "Reasonable and Necessary" and NCDs

Often, liability in cases based on allegations of overtreatment depends largely upon where, exactly, the line lies between legitimate and illegitimate care. In these cases, determining what is legal depends upon what is medically necessary.⁸⁹ Where providers "on the ground" differ from Medicare's medical necessity standards, a conflict of law and medicine results — a conflict that, professional organizations will unsurprisingly argue, should be resolved in favor of the individual clinician's judgment.⁹⁰ That allegations of overtreatment can result in

August-2011.pdf ("CMS should be allowed to deny coverage and/or reduce the pricing for technologies that provide health outcomes comparable to already covered, but less costly, technologies."); Fox, *Medicare Should Consider Cost*, *supra* note 72, at 595-96; see also Steven D. Pearson & Peter B. Bach, *How Medicare Could Use Comparative Effectiveness Research in Deciding on New Coverage and Reimbursement*, 29 HEALTH AFF. 1796, 1796 (2010).

⁸⁸ See Fox, *Medicare Should Consider Cost*, *supra* note 72, at 603-09.

⁸⁹ As a result, this analysis — and the global suggestions posited here — focuses solely on cases whose alleged fraudulent acts hinge on an analysis of whether a procedure was medically necessary or not. Although interesting, cases in which providers and entities brazenly defraud the federal government are not those on which this analysis focuses. These include cases in which individuals open fake storefronts in Miami and bill the federal government for care they never administered, "crooked" doctors "upcode" the bill they send in for reimbursement, and pharmacists bill for brand-name drugs but fill patients' prescriptions with generic alternatives. See Chris Parker, *South Florida Is Ground Zero for Medicare Fraud*, MIAMI NEW TIMES (May 2, 2013), <http://www.miaminewtimes.com/2013-05-02/news/medicare-fraud-south-florida/full/>; see also Andrea K. Walker, *Medical Billing a Target of Fraud Investigations*, BALTIMORE SUN (Jan. 12, 2012), http://articles.baltimoresun.com/2012-01-12/health/bs-hs-umms-malnutrition-response-2-20120112_1_health-care-fraud-coding-billing; *Authorities Crackdown on Major Medicare Fraud In Detroit*, KAISER HEALTH NEWS (June 25, 2009), <http://www.kaiserhealthnews.org/daily-reports/2009/june/25/more-fraud.aspx> ("The scheme in Miami allegedly used fake storefronts in an attempt to cheat Medicare out of \$100 million."); *Twin-Brother Pharmacists Admit Guilt in \$1.5M Health Care Fraud*, NJ.COM (Aug. 6, 2013), http://www.nj.com/essex/index.ssf/2013/08/twin-brother_pharmacists_admit_guilt_in_15m_health_care_fraud.html. These are clear cases of deceit, and the insights presented here do not apply to these actors. Their prosecution and punishment are less doctrinally challenging — and, of course, largely not responsible for the avalanche of cost challenges facing Medicare.

⁹⁰ See Richard I. Fogel et al., *The Disconnect Between the Guidelines, the Appropriate Use Criteria, and Reimbursement Coverage Decisions*, 63 J. AM. C. CARDIOLOGY 12, 14

dramatic legal consequences for the providers targeted highlights the importance of Medicare's medical necessity determination.⁹¹ Still, this important process has been described as being "maintained in secrecy"⁹² and "closeted."⁹³

By statutory design, Medicare provides scant guidance for clinicians. In fact, the Medicare statute requires that:

Nothing in this subchapter shall be construed to authorize any Federal officer or employee to exercise any supervision or control over the practice of medicine or the manner in which medical services are provided, or over the selection, tenure, or compensation of any officer or employee of any institution, agency, or person providing health services; or to exercise any supervision or control over the administration or operation of any such institution, agency, or person.⁹⁴

Predictably, by ceding "any supervision or control" over the "practice of medicine or the manner in which medical services are provided," Medicare has limited its ability to control costs.⁹⁵ Beyond the general prohibition of government involvement in medicine, Medicare's standard-setting function also is statutorily-based. "[N]o payment may be made . . . for any expenses incurred for items or services which . . . are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member."⁹⁶ The "reasonable and necessary" language is not defined by the statute,⁹⁷ but the requirement that a service be reasonable or

(2014).

⁹¹ See Sandra H. Johnson, *Regulating Physician Behavior: Taking Doctors' "Bad Law" Claims Seriously*, 53 ST. LOUIS U. L.J. 973, 1029 (2009) [hereinafter *Regulating Physician Behavior*] (noting that providers subject to a fraud investigation suffer a number of financial and reputational costs).

⁹² See Timothy P. Blanchard, "Medical Necessity" Determinations — A Continuing Healthcare Policy Problem, 37 J. HEALTH L. 599, 604 (2004).

⁹³ See Fox, *The Hidden Role of Cost*, *supra* note 39, at 50.

⁹⁴ 42 U.S.C. § 1395 (2012).

⁹⁵ *Id.*; see also William J. Scanlon, *The Future of Medicare Hospital Payment*, 25 HEALTH AFF. 70, 71 (2006) ("The program has also been reluctant to question the value of services and whether some should be purchased at all, a reflection, perhaps, of its historical mandate 'not to interfere in the practice of medicine.'").

⁹⁶ 42 U.S.C.A. § 1395y (West 2014).

⁹⁷ See DeBoer, *supra* note 38, at 504-05 ("The Medicare statute does not define the term 'reasonable and necessary' or specific criteria for making coverage determinations.").

necessary is the “major criterion for coverage of benefits” within the Medicare program.⁹⁸

When providers submit the “CMS-1500 Form” — the form they use to bill Medicare for an administered health care service — they must certify that the services billed on the form “were medically indicated and necessary for the health of the patient.”⁹⁹ Where the provider certifies as such, and Medicare pays for the service, but that service was “not reasonable and necessary for the diagnosis or treatment of illness or injury,” then the certification is false. When submitted, the provider is making a false statement to the federal government, which triggers potential FCA liability.¹⁰⁰

For many services, Medicare’s sole reimbursement standard is the statutory “reasonable and necessary” standard. But, for particular services, Medicare provides specific coverage determinations beyond the statutory language. Primarily for Medicare Part B, which includes reimbursement for participating providers, the program establishes codes for particular services for which it will reimburse.¹⁰¹ For about

⁹⁸ Kinney, *supra* note 50, at 1463.

In 2009, the Court of Appeals for the D.C. Circuit clearly held that, due to the language and structure of the Medicare statute, CMS is prohibited from only covering the “least costly alternative” in the Medicare program. *See Hays v. Sebelius*, 589 F.3d 1279, 1279 (D.C. Cir. 2009). In the case, a Medicare beneficiary had challenged a Medicare determination that allowed for reimbursement for a particular prescription “only up to the price of its least costly alternative.” *Id.* The D.C. Circuit agreed with the beneficiary, noting that, due to the wording of the Medicare statute, “reasonable and necessary” did not modify “expenses,” but rather, only modifies “items or services.” *Id.* at 1281; *see also* Fox, *The Hidden Role of Cost*, *supra* note 39, at 45 (suggesting that the statute be rewritten to allow for cost to be considered in coverage policy).

The *Hays* holding, of course, prevents the Secretary of Health and Human Services from reimbursing for a drug at a cheaper alternative’s rate; instead, she can “make only a binary choice: either an item or service is reasonable and necessary, in which case it may be covered at the statutory rate, or it is unreasonable or unnecessary, in which case it may not be covered at all.” *Hays*, 589 F.3d at 1283. Further, on a more important note, as has been previously argued, it cannot be the case that “reasonable” within the statute can be read to “include what it is reasonable to pay for, at least going so far as to allow CMS the right to consider cost effectiveness of new treatment” due to the historical development of the program. Fox, *The Hidden Role of Cost*, *supra* note 39, at 46.

⁹⁹ *See* CTRS. FOR MEDICARE & MEDICAID SERVS., CMS-1500: HEALTH INSURANCE CLAIM FORM (2005), available at <http://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/downloads/CMS1500805.pdf>.

¹⁰⁰ *See* 31 U.S.C. § 3729 (2012) (making illegal either “false or fraudulent claim[s]” or “false record[s] or statement[s]”).

¹⁰¹ Timothy Stoltzfus Jost, *The Medicare Coverage Determination Process in the United States*, in HEALTH CARE COVERAGE DETERMINATIONS: AN INTERNATIONAL

one-quarter of newly-developed codes, Medicare establishes an NCD, which provides some limitation on, or specification for, the reimbursable service.¹⁰² NCDs are universally applicable, and are subject to a formal rulemaking process.¹⁰³ Beyond NCDs, regional and/or local Medicare contractors can issue LCDs¹⁰⁴ for particular parts of the country, based upon the medical standards of care, research findings, expert opinion, and advice from other associations.¹⁰⁵ These are applicable only in certain geographic areas.¹⁰⁶

When creating NCDs, Medicare has rejected previous attempts to explicitly consider cost effectiveness,¹⁰⁷ and as a result, Medicare now does not consider the cost effectiveness of most reimbursable benefits.¹⁰⁸ Medicare has clearly stated, “[c]ost effectiveness is not a factor CMS considers in making NCDs. In other words, the cost of a particular technology is not relevant in the determination of whether the technology improves health outcomes or should be covered for the Medicare population through an NCD.”¹⁰⁹

Medicare’s NCD process was updated in the summer of 2013,¹¹⁰ but still provides no consideration of cost effectiveness when evaluating new services. Despite recent claims, “there is little evidence that Medicare denies coverage of effective technologies solely on the basis of cost.”¹¹¹ Further, researchers have found “no clear evidence of an implicit threshold” of cost-effectiveness when evaluating NCD applications.¹¹²

In addition to the lack of cost consideration in determining NCDs, other procedurally-based characteristics of the NCD application process confer an advantage on those who want CMS to approve and create an NCD for new, potentially expensive procedures and

COMPARATIVE STUDY 209, 211 (Timothy Soltzhus Jost ed., 2005).

¹⁰² *Id.* at 212.

¹⁰³ See Blanchard, *supra* note 92, at 615 (describing the “formal process”); see also DeBoer, *supra* note 38, at 512 (laying out “coverage decision-making processes”).

¹⁰⁴ DeBoer, *supra* note 38, at 506.

¹⁰⁵ Jost, *supra* note 101, at 212-13.

¹⁰⁶ See *id.*

¹⁰⁷ See *id.* at 217-18.

¹⁰⁸ See *id.* at 230.

¹⁰⁹ CTRS. FOR MEDICARE & MEDICAID SERVS., FACTORS CMS CONSIDERS IN OPENING A NATIONAL COVERAGE DETERMINATION (2006), available at <http://www.cms.gov/medicare-coverage-database/details/medicare-coverage-document-details.aspx?MCDId=6&McdName=Factors+CMS+Considers+in+Opening+a+National+Coverage+Determination>.

¹¹⁰ See *Medicare Coverage Determination Process*, *supra* note 82.

¹¹¹ Jost, *supra* note 101, at 219.

¹¹² See Chambers et al., *supra* note 85, at E14.

products. Specifically, there are “multiple entry points into” the reimbursement methodology available to manufacturers, allowing “proponents of a new technology to intervene more aggressively when they see things going badly.”¹¹³ Further, proponents of coverage of new technologies “have multiple levers to take action if they see the process going astray.”¹¹⁴ Finally, few opponents of coverage determinations exist, given the lack of interest by any one individual or group to argue *against* the broadening of coverage determinations.¹¹⁵ All these factors make the process “poorly suited for making cost-benefit calculi” and allows for “many opportunities to game the system.”¹¹⁶

Other challenges hamper Medicare’s coverage determinations. A scholar has noted that coverage decisions are not designed to be necessarily “accurate,” and instead are “political decision[s].”¹¹⁷ Consequently, reviewing courts must ask whether coverage determinations were “reasonable” instead of “accurate.”¹¹⁸ For its part, CMS argues that criteria have been adopted to evaluate NCD applications, but others have pointed out that these criteria are not formalized or published.¹¹⁹ Finally, the concerns surrounding the NCD process are compounded by the fact that Medicare — in many instances — seems willing to initially pay for services that are not covered by the program. In a number of recent overtreatment cases, even though the particular provider’s care did not comply with Medicare’s applicable NCD, the program still paid for the service administered, only for the DOJ to investigate the administered service years later.¹²⁰

Particularly for services for which an NCD has not been established — and the services that are allegedly not in compliance with Medicare’s medical necessity determination — Medicare seems trapped by its requirement to pay out on claims quickly.¹²¹ Required

¹¹³ Jost, *supra* note 101, at 229-30.

¹¹⁴ *Id.*

¹¹⁵ *See id.*

¹¹⁶ *Id.*

¹¹⁷ Kinney, *supra* note 50, at 1500.

¹¹⁸ *Id.*

¹¹⁹ *See* Michael S. Kolber, *Opacity and Cost Effectiveness Analysis in Medicare Coverage Decisions: Health Policy Encounters Administrative Law*, 64 FOOD & DRUG L.J. 515, 515 (2009).

¹²⁰ *See* Buck, *Caring Too Much*, *supra* note 23, at 496-99.

¹²¹ *See* T.R. GOLDMAN, HEALTH AFFAIRS, HEALTH POLICY BRIEF: ELIMINATING FRAUD AND ABUSE 2 (2012), available at http://healthaffairs.org/healthpolicybriefs/brief_pdfs/healthpolicybrief_72.pdf (noting that Medicare was “designed to enroll ‘any

to immediately pay providers for care administered, the program has historically relied on the “pay and chase” method of fraud and abuse enforcement.¹²² This creates the baffling potential situation where Medicare has not provided a positive coverage determination or has otherwise limited the types of services for which it will reimburse, but still quickly pays for an uncovered service.

This complicates the participating providers’ views of Medicare’s standard-setting function. Providers may think that Medicare either does not have the will — or the personnel — to actually enforce its NCD standards; it will pay anyway. From a legal perspective, this clouds the analysis. Under traditional contract law, Medicare would have a difficult time challenging the quality of the service rendered *after* it pays for it. By paying for the service, Medicare seems to be satisfied by the care administered. Further, by receiving reimbursement for the service, providers mistakenly believe that the service is reasonable and necessary. Indeed, if it weren’t, Medicare would not have paid for it. When this medical necessity determination is already ambiguous — or impacted heavily by minor details — Medicare’s prompt payment may encourage providers to continue administering the procedure in a certain way that the DOJ will characterize as health care fraud later.

II. TAKING ADVANTAGE OF NEW TRANSPARENCY

This proposal advocating a shift in the focus of overtreatment regulation coincides with the beginning of a new era of increased transparency surrounding what particular providers charge to — and pocket in profit due to their participation in — the Medicare program. As Medicare’s data-driven era begins in earnest, a corresponding recalibration of legal accountability seems timely and appropriate. In some ways, newly-released figures beg for reasoned-but-swift legal regulation.

For example, the top ten physicians who charged Medicare the most received more than \$121 million in Part B reimbursement from the program in 2012.¹²³ Notwithstanding the particular details of the providers’ bills, it would appear that the government would be

willing provider’ and to reimburse claims quickly for the services provided. . . . The emphasis on rapid payment, as opposed to identifying and rooting out false or inflated claims, makes both programs susceptible to fraud”).

¹²² *Id.* at 1.

¹²³ See Jason Millman, *The Top 10 Medicare Billers Explain Why They Charged \$121M in One Year*, WASH. POST (Apr. 9, 2014), <http://www.washingtonpost.com/blogs/wonkblog/wp/2014/04/09/the-top-10-medicare-billers-explain-why-they-charged-121m-in-one-year/>.

interested in pursuing regulatory solutions. Indeed, just 2% of physicians are responsible for 25% of all Medicare payments.¹²⁴

Unfortunately, these new data demonstrate the cost challenges facing the program, but also highlight the fact that there is no sufficient agency-based regime in place to address them. This is particularly shown by the fact that much of the waste highlighted by the data releases is a result of administered care that has been legally delivered *in compliance with* Medicare's NCD determinations. Consequently, the imminent challenge of improving overtreatment regulation must concern itself with building a calibrated framework in an attempt to deter and prevent some of the program's most wasteful but currently legal abuses — without harming Medicare's quality.

This new era of transparency within Medicare has been demonstrated by two occurrences: (1) a newly released report that shows the main sources of waste within the Medicare program;¹²⁵ and (2) a massive data release in the spring of 2014 that documented providers' patterns of billing and utilization, illustrating each physician's total billed amount to Medicare in 2012.¹²⁶ A summary of both — highlighting the scope of the challenge facing Medicare and the need for a reasoned legal solution — is central to this analysis.

A. Waste in Plain Sight

The June 2014 Medicare Payment Advisory Commission ("MedPAC")¹²⁷ report, entitled "A Data Book: Health Care Spending and the Medicare Program," noted the financial challenges facing the

¹²⁴ See Brett Norman, *Release of Medicare Pay Data Puts Hard Focus on Top-Billers*, POLITICO (Apr. 9, 2014, 5:01 AM EDT), <http://www.politico.com/story/2014/04/medicare-pay-data-laid-bare-105500.html>.

¹²⁵ See MEDICARE PAYMENT ADVISORY COMM'N, A DATA BOOK: HEALTH CARE SPENDING AND THE MEDICARE PROGRAM 14 (2014) [hereinafter A DATA BOOK].

¹²⁶ See *Medicare Provider Utilization and Payment Data*, CTRS. FOR MEDICARE & MEDICAID SERVS., <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Medicare-Provider-Charge-Data/> (last modified Apr. 9, 2014).

¹²⁷ According to its website:

[MedPAC] is an independent congressional agency . . . to advise the U.S. Congress on issues affecting the Medicare program. The Commission's statutory mandate is quite broad: In addition to advising the Congress on payments to private health plans participating in Medicare and providers in Medicare's traditional fee-for-service program, MedPAC is also tasked with analyzing access to care, quality of care, and other issues affecting Medicare.

About MedPAC, MEDICARE PAYMENT ADVISORY COMM'N, <http://www.medpac.gov/about-medpac-> (last visited Dec. 30, 2014).

program.¹²⁸ In addition to generally demonstrating the rising costs *per capita* within Medicare, it also pointed out which particular procedures were most subject to the highest volume and expenditure.¹²⁹

Generally, as has been widely reported,¹³⁰ health care costs have “relentless[ly]” increased,¹³¹ and are projected to continue to do so.¹³² In 1966, health care spending was “about 6 percent” of GDP, and in 2009, it was 17%.¹³³ “Projections suggest that total health care spending will make up about 19% of GDP by 2022.”¹³⁴

Medicare alone made up 23% of overall personal health care spending in 2012,¹³⁵ making it the “largest single purchaser of health care in the United States.”¹³⁶ Its share of GDP rose from less than 1% in 1966 to 3.5% of GDP in 2012¹³⁷ — and the program is projected to exceed 5% in 2030 and 6% of GDP in 2080.¹³⁸ The escalating expense is largely due to a quickly increasing population of beneficiaries; “[t]he rapid growth in the number of beneficiaries began in 2011 and will continue through 2030 as members of the baby-boom generation

¹²⁸ A DATA BOOK, *supra* note 125, at 14.

¹²⁹ See *id.* at 101 (noting that diagnostic cardiac catheterization, cataract procedures with IOL insert, and Level I plain film except teeth are the most expensive and highest-volume procedures).

¹³⁰ See, e.g., Paul Davidson, *Health Care Spending Growth Hits 10-Year High*, USA TODAY (Apr. 1, 2014, 6:51 PM EDT), <http://www.usatoday.com/story/money/business/2014/03/30/health-care-spending/7007987/> (noting that “[h]ealth care spending rose at the fastest pace in 10 years [in the fourth quarter of 2013]”).

¹³¹ Noam N. Levey, *U.S. Healthcare Costs Keep Rising But at Slower Pace*, L.A. TIMES (Jan. 6, 2014), <http://www.latimes.com/business/la-fi-0107-healthcare-spending-20140107-story.html> (noting “moderate” rising costs in most recent quarters, but noting that, in twelve of the past fifteen years, health spending grew more quickly than the larger economy); see also Reid Wilson, *Health Care Spending Still Rising for States and Cities*, WASH. POST (Jan. 31, 2014), <http://www.washingtonpost.com/blogs/govbeat/wp/2014/01/31/health-care-spending-still-rising-for-states-and-cities/> (noting that “health-care spending is consuming a greater percentage of state and local government budgets than at any time since the Centers for Medicare and Medicaid Services began collecting data”).

¹³² See A DATA BOOK, *supra* note 125, at 7.

¹³³ *Id.*

¹³⁴ *Id.*

¹³⁵ *Id.* at 5.

¹³⁶ *Id.*

¹³⁷ *Id.* at 7.

¹³⁸ *Id.* at 8. The Social Security and Medicare Boards of Trustees forecast that Medicare spending could approach 7% of GDP by 2088. See *A Summary of the 2014 Annual Reports*, SOC. SEC. ADMIN., <http://www.ssa.gov/oact/trsum/> (last visited Aug. 13, 2014).

reach age 65 and become eligible to receive benefits,” according to MedPAC.¹³⁹ Indeed, using Part A enrollment figures, MedPAC has noted that “[t]he total number of people enrolled in the Medicare program will increase from about 50 million in 2012 to about 81 million in 2030.”¹⁴⁰ Aside from the rising future enrollment in the program, utilization rates and the cost associated with those services continue to rise; “Medicare spending among [fee-for-service] beneficiaries has increased significantly since 2003,” according to the report.¹⁴¹

The two most expensive sectors of the Medicare program are, predictably, hospital inpatient and physician payments.¹⁴² Inpatient spending among fee-for-service beneficiaries per capita jumped from \$3,144 in 2003 to \$3,632 in 2012 (although that was down from a high of \$3,764 in 2009), whereas the same metric for physician reimbursement rose from \$1,461 in 2003 to \$2,134 in 2012.¹⁴³ Just 25% of the most expensive fee-for-service beneficiaries are responsible for 82% of the total program spending.¹⁴⁴ In total, hospital inpatient payment increased from \$111 billion in 2003 to \$135 billion in 2011.¹⁴⁵ Physician reimbursement climbed from \$49 billion in 2003 to \$70 billion in 2012.¹⁴⁶

Specific to physician reimbursement, Medicare spending increases have been caused by growth in the amount of procedures administered.¹⁴⁷ Per beneficiary, Medicare’s expenditures for physician services raised 72% from 2000 to 2012.¹⁴⁸ Further, the volume of tests administered raised 90% from 2000 to 2012, and imaging volume increased 73% during those same years per beneficiary.¹⁴⁹ This led MedPAC to conclude that these “volume increases translate directly to growth in Part B spending and premiums. They are also largely responsible for the negative updates required by the sustainable

¹³⁹ A DATA BOOK, *supra* note 125, at 8; see also Richard Wolf, *Medicare to Swell with Baby Boomer Onslaught*, USA TODAY (Dec. 30, 2010), http://usatoday30.usatoday.com/news/washington/2010-12-30-medicare30_ST_N.htm (noting that Baby Boomer aging will increase Medicare spending).

¹⁴⁰ A DATA BOOK, *supra* note 125, at 22.

¹⁴¹ *Id.* at 3.

¹⁴² See *id.* at 4.

¹⁴³ See *id.*

¹⁴⁴ See *id.* at 12.

¹⁴⁵ *Id.* at 3.

¹⁴⁶ *Id.*

¹⁴⁷ See *id.* at 90.

¹⁴⁸ *Id.*

¹⁴⁹ *Id.* at 96.

growth rate formula. Rapid volume growth may be a sign that some services in the physician fee schedule are mispriced.”¹⁵⁰

Other numbers in the report confirmed the phenomenon that when Medicare pays for it, utilization increases.¹⁵¹ Of particular note, both CT and magnetic resonance imaging (“MRI”) scans ballooned between 2000 and 2012 — with CT scans on parts of the body other than the head increasing 114%, and MRIs on parts of the body other than the brain raising 122%.¹⁵² Both CTs and MRI scans were reflected in the top twenty most expensive hospital outpatient services for Medicare — with these twenty services making up 44% of total payments made in the ambulatory payment classification (“APC”).¹⁵³

B. High Utilizers

For the first time since 1979,¹⁵⁴ and after the American Medical Association (“AMA”) “chose not to try to block the release of the information”¹⁵⁵ after doing so for thirty-five years,¹⁵⁶ Medicare released annual provider biller and utilization data for 2012 to the public in a massive disclosure in the spring of 2014. Months later, CMS released data listing what different hospitals nationwide charge for “some of the most common inpatient procedures.”¹⁵⁷ These data represented a total of more than \$77 billion in payments within Part B fee-for-service reimbursement to more than 880,000 health care providers.¹⁵⁸ Total

¹⁵⁰ *Id.*

¹⁵¹ *Cf. id.* at 104 (presenting that observation hours more than doubled between 2006 and 2012, following changes that made the hours easier to count in 2006 and changes that paid separately for observation hours starting in 2002).

¹⁵² *See id.* at 107.

¹⁵³ *Id.* at 101.

¹⁵⁴ *See* Chad Terhune et al., *Release of Medicare Doctor Payments Shows Some Huge Payouts*, L.A. TIMES (Apr. 8, 2014, 9:00 PM), <http://www.latimes.com/business/la-fi-medicare-doctor-pay-20140409-story.html>.

¹⁵⁵ Reed Abelson & Sarah Cohen, *Sliver of Medicare Doctors Get Big Share of Payouts*, N.Y. TIMES (Apr. 9, 2014), <http://www.nytimes.com/2014/04/09/business/sliver-of-medicare-doctors-get-big-share-of-payouts.html>.

¹⁵⁶ *See* Joe Carlson, *CMS Reveals Medicare Physician Pay Data*, MODERN HEALTHCARE (Apr. 9, 2014), <http://www.modernhealthcare.com/article/20140409/NEWS/304099954> [hereinafter *CMS Reveals*].

¹⁵⁷ *See* Julie Creswell et al., *Hospital Charges Surge for Common Ailments, Data Shows*, N.Y. TIMES (June 2, 2014), <http://www.nytimes.com/2014/06/03/business/Medicare-Hospital-Billing-Data-Is-Released.html>. Although these data may have limited utility and relevance to what Medicare ultimately pays for a procedure (after a series of negotiations regarding payments), it still highlights the growing recognition of spiraling and inconsistent cost structures. *See id.*

¹⁵⁸ *See* Press Release, Ctrs. for Medicare & Medicaid Servs., *Historic Release of*

payments to doctors totaled almost \$64 billion, with more than \$12 billion going toward paying for office and outpatient visits.¹⁵⁹

The media immediately noted those providers with the highest reimbursement totals through the program, calling Medicare “the source of a small fortune for many U.S. doctors.”¹⁶⁰ Collectively, the fortune was not small; doctors with the highest reimbursement amounts were responsible for about \$15 billion of the total payments made by Medicare — “roughly a quarter of the total [Medicare payments].”¹⁶¹ The data allowed the public to search for its health care providers, and also led many to believe that “[r]egulators and others are . . . likely to seize on some of this information to find those doctors who perform an unusually high volume of services.”¹⁶² Unsurprisingly, according to the Washington Post, of the top ten Medicare earners, three “already had drawn scrutiny from the federal government.”¹⁶³

Criticism of the data release was swift. AMA President Ardis Dee Hoven noted that “the broad data dump . . . [has] significant shortcomings regarding the accuracy and value of the medical services rendered by physicians.”¹⁶⁴ The AMA is concerned about “inaccuracies, misinterpretations, false conclusions, and other unintended consequences,” he noted.¹⁶⁵ And his concerns are not insubstantial; for example, some doctors in a large physician practice may bill under one single physician code, greatly distorting the amount for which each provider is responsible.¹⁶⁶ Sums also commonly go to other employees’ salaries, taxes, overhead costs, and

Data Gives Consumers Unprecedented Transparency on the Medical Services Physicians Provide and How Much They Are Paid (Apr. 9, 2014), *available at* <http://www.cms.gov/Newsroom/MediaReleaseDatabase/Press-releases/2014-Press-releases-items/2014-04-09.html>; *see also* Terhune et al., *supra* note 154.

¹⁵⁹ *See* Abelson & Cohen, *supra* note 155; Dan Keating et al., *Database: How Much Medicare Pays Doctors*, WASH. POST (Apr. 9, 2014), <http://www.washingtonpost.com/wp-srv/special/national/medicare-doctors-database/>.

¹⁶⁰ *See* Peter Whoriskey et al., *Data Uncover Nation’s Top Medicare Billers*, WASH. POST (Apr. 9, 2014), http://www.washingtonpost.com/business/economy/data-uncover-nations-top-medicare-billers/2014/04/08/9101a77e-bf39-11e3-b574-f8748871856a_story.html.

¹⁶¹ *See* Abelson & Cohen, *supra* note 155.

¹⁶² *Id.*

¹⁶³ Whoriskey et al., *supra* note 160.

¹⁶⁴ Carlson, *CMS Reveals*, *supra* note 156.

¹⁶⁵ *Id.*

¹⁶⁶ *See id.*; Millman, *supra* note 123 (noting that many physicians who are in the top ten are there because their names are used for billing purposes to represent the work of multiple physicians).

patient drugs.¹⁶⁷ However, presumably, more sophisticated data will allow regulators to exclude from investigation those providers whose additional data demonstrate one of these uncommon arrangements.

Notwithstanding these concerns, the data release allows government regulators, and surely the public, to apply pressure to those who are most responsible for a substantial segment of Medicare's rising expenses. If nothing else, it exposes those who are most responsible for high utilization rates. The release also highlights the current vacuum of legal tools available to the overseeing agencies to limit costs; again, Medicare seems powerless.

III. IN SEARCH OF A STANDARD

Fraught with process-based complications, Medicare struggles to slow cost growth through its statutorily-constrained channels. For its part, the DOJ — through its regulation of overtreatment — has relied on Medicare's NCDs to decide which providers to target for investigations. But leaning on NCDs to determine the targets of an overtreatment investigation may both: (1) increase the regime's susceptibility to disorder and overuse because of the inaccuracy of the program's coverage determinations; and (2) prevent the DOJ from casting a wider, but more accurate, net to discourage providers from administering expensive procedures and ordering costly products. As currently constituted, the legal framework seems to suggest that a doctor's repeated administration of a substantially above-average number of procedures does not, by itself, make that care medically unnecessary.

In order to propose a new construct of overtreatment regulation, it is worthwhile to examine current and recent overtreatment investigations to understand the tension that results from use of the medical necessity standard; two such investigations are summarized below. In one, the nationwide implantable cardioverter defibrillator ("ICD") investigation features a scenario in which the DOJ has used Medicare's applicable NCD standard as the initial governing standard in an effort to separate physicians engaged in health care fraud from physicians providing legitimate treatment.¹⁶⁸ In the second example, no applicable NCD governs, but allegations are made that the care at issue was not medically necessary. Both follow below.

¹⁶⁷ See Millman, *supra* note 123.

¹⁶⁸ See Buck, *Caring Too Much*, *supra* note 23, at 492-93; Buck, *Enforcement Overdose*, *supra* note 25, at 277.

A. *Reimbursement Standards as Law*

Now into its fourth year, the DOJ's nationwide investigation of ICDs has resulted in one settlement thus far with now-defunct Medcath Corporation for \$6 million.¹⁶⁹ "Hundreds of unresolved cases" are pending.¹⁷⁰ Although at this point, the DOJ is formerly investigating only hospitals, officials "may eventually look past the hospitals where implantations took place and target the doctors recommending the devices to patients"¹⁷¹ for potential liability, according to those involved with the investigations.

Specifically, the investigation is targeting providers who placed an ICD — a highly-expensive device,¹⁷² for which Medicare pays — outside of Medicare's NCD standard.¹⁷³ Most basically, these providers placed an ICD in the chest of a patient within Medicare's mandatory waiting period.¹⁷⁴ After the investigation, a number of clinics and hospitals have defended their providers' determinations that ICDs were medically necessary and appropriate — even those not in compliance with Medicare's NCD timing requirements.¹⁷⁵ As the nationwide investigation has continued, it has provided an example of what happens when an NCD splits from a clinical standard "on the ground" and that split results in a nationwide health care fraud investigation.

In this case, Medicare's NCD required a waiting period of a minimum number of days between an adverse cardiac event and the ICD placement, but the investigation has revealed that a number of providers did not comply with that standard.¹⁷⁶ In particular, Medicare's applicable NCD standard governing ICD placement — and

¹⁶⁹ See Joe Carlson, *Investigation into Overuse of Heart Devices Credited with Lowering Number of Procedures*, MODERN HEALTHCARE (Jan. 28, 2014), <http://www.modernhealthcare.com/article/20140128/NEWS/301289915>. Interestingly, however, the DOJ has made no publicly-available statement regarding the existence of this settlement.

¹⁷⁰ *Id.*

¹⁷¹ *Id.*

¹⁷² See A DATA BOOK, *supra* note 125, at 101 (listing "cardioverter-defibrillator implantation" — and the "insertion/replacement/repair of cardioverter-defibrillator leads" as the most expensive procedures as part of the "ambulatory payment classification" within Medicare).

¹⁷³ For more information on the investigation, see Buck, *Enforcement Overdose*, *supra* note 25, at 277-83. For more information about how Medicare came to the coverage decision for ICDs, see Fox, *The Hidden Role of Cost*, *supra* note 39, at 25-30.

¹⁷⁴ See Buck, *Enforcement Overdose*, *supra* note 25, at 277-79.

¹⁷⁵ *Id.*

¹⁷⁶ *Id.*

requiring the waiting period — was last revised in 2005.¹⁷⁷ Conversely, the American College of Cardiology (“ACC”), American Heart Association (“AHA”), and the Heart Rhythm Society (“HRS”) have established guidelines numerous times, first promulgating “general” guidelines for practitioners in 1984 and since updating them in 1991, 1998, 2002, 2008, 2012,¹⁷⁸ and again in 2013.¹⁷⁹

Further, breaking from Medicare’s NCD, the ACC and HRS “have developed appropriate use criteria (“AUC”) to adjudicate the appropriateness of ICD implantation” to further aid clinicians in relatively common scenarios.¹⁸⁰ The AUC process is purportedly “rigorous” and “incorporates evidence based medicine.”¹⁸¹ Adversely, the 2005 Medicare NCD “does not address many of the scenarios for primary-prevention ICD use that were considered appropriate by the AUC authors.”¹⁸² As such, providers and hospitals that placed ICDs at certain timing intervals were likely in compliance with the AUC — the standard promulgated by three professional organizations — but not with Medicare’s NCD, and, as a result of billing Medicare for the placements, have faced fraud investigations. The investigation has highlighted the battle between providers and regulators over who should control clinical standards, with the profession arguing for the autonomy of the physicians and the defensibility of the hospitals, and the government first taking a particularly aggressive approach, and then exempting certain providers and clinics who committed “technical violations” from liability.¹⁸³

This, of course, is a signal from the DOJ that the Medicare NCD may *not* represent the most accurate line between legitimate care and fraud. If a provider can violate Medicare’s NCD but be exempted from fraud prosecution, the DOJ appears to be recognizing that there is room between the standards. Indeed, if there is room between the standards — meaning that some providers did not comply with an NCD but who are no longer targets of a health care fraud investigation — then it

¹⁷⁷ See Fogel et al., *supra* note 90, at 13.

¹⁷⁸ See *id.*

¹⁷⁹ See Andrea M. Russo et al., *ACCF/HRS/AHA/ASE/HFSA/SCAI/SCCT/SCMR 2013 Appropriate Use Criteria for Implantable Cardioverter-Defibrillators and Cardiac Resynchronization Therapy*, 10 HEART RHYTHM e11 (2013).

¹⁸⁰ See Fogel et al., *supra* note 90, at 13.

¹⁸¹ *Id.*

¹⁸² *Id.*

¹⁸³ See Buck, *Enforcement Overdose*, *supra* note 25, at 280-81 (presenting the DOJ’s proposed settlement framework with providers who committed only a “technical violation”).

indicates that the NCD does not represent the most current and accurate clinical standard. Still, the picture is not completely clear; some of the providers arguing for autonomy in these investigations have financial relationships with some ICD manufacturers¹⁸⁴ — a fact that undoubtedly complicates the analysis.

Nevertheless, the ICD investigation highlights the potential difficulty in basing an overtreatment investigation on a Medicare NCD. Affected by delays and shifting standards for liability, it is currently unclear which providers — and as a result, hospitals and clinics — committed health care fraud by virtue of placing ICDs in violation of Medicare's NCDs. After four years of investigation, providers are still waiting for resolution of these allegations.

B. Medical Necessity Regulation

On its website, EMH Elyria Medical Center ("EMH") in suburban Cleveland boasts that it "has received numerous awards for quality of care, operational efficiency, financial performance, and adaptation to the environment."¹⁸⁵ But in 2006, EMH was under a cloud of suspicion; it was allegedly responsible for the fact that Medicare patients in Elyria were administered angioplasties four times more than the national average, and three times more than the state average.¹⁸⁶ EMH's cardiology clinic, the North Ohio Heart Center ("NOHC"), was largely responsible for the high rate.¹⁸⁷ Unsurprisingly, cardiologists at NOHC had a self-admitted "unabashed enthusiasm for angioplasties"¹⁸⁸ — indeed, according to them, the higher rate was "simply a function of . . . doctors' detecting disease more often in their patients than physicians elsewhere might

¹⁸⁴ Seven of nine authors on a recent viewpoint article that present this conflict have received honoraria, grants, fellowship support, or research support, have been consultants for, and/or have equity in, Biotronic, Boston Scientific, Medtronic, and/or St. Jude Medical — all four entities manufacture and market ICDs. See Fogel et al., *supra* note 90, at 12. Additionally, five of those same authors — with perhaps the same relationships with the ICD manufacturers at the time of the writing — authored the 2013 AUC guidelines. Compare *id.* at 1 (listing Andrew E. Epstein, Bruce D. Lindsay, Mark S. Kremers, Suraj Kapa, and Andrea M. Russo as co-authors), with Russo et al., *supra* note 179 (same).

¹⁸⁵ See Awards, UNIV. HOSPS. ELYRIA MED. CTR., <http://www.uhhospitals.org/elyria/about/awards> (last visited Aug. 23, 2013).

¹⁸⁶ See Reed Abelson, *Health Procedure Is Off the Charts in an Ohio City*, N.Y. TIMES (Aug. 18, 2006), <http://www.nytimes.com/2006/08/18/business/18stent.html> [hereinafter *Health Procedure*].

¹⁸⁷ See *id.*

¹⁸⁸ *Id.*

spot, and being quicker to intervene.”¹⁸⁹ Dr. John Schaeffer, the founder and president of NOHC, said NOHC “manage[d] very aggressively the patients we care[d] for” and “[w]e ha[d] excellent outcomes.”¹⁹⁰

Perhaps predictably, this “aggressiveness” drew a *qui tam*¹⁹¹ relator’s lawsuit under the False Claims Act (“FCA”),¹⁹² with the relator alleging that by administering excessive angioplasties and placing medically unnecessary stents, the doctors at NOHC had violated the law.¹⁹³ This was followed by a years-long DOJ investigation that ultimately resulted in a \$4.4 million settlement.¹⁹⁴ The DOJ’s accompanying announcement noted that the settlement agreement “resolve[d] allegations that between 2001 and 2006 EMH and NOHC performed unnecessary cardiac procedures on Medicare patients.”¹⁹⁵

For their part, cardiologists at NOHC defended their “high-quality care.”¹⁹⁶ According to their statements, the doctors at NOHC believed in the efficacy of the drug-coated stents they placed, using them even when other physicians may have recommended a more-expensive bypass surgery. What complicated the analysis in 2006 was the dearth of studies that conclusively showed which approach — stents, drugs, or bypass surgery — was most effective in the long term.¹⁹⁷ In addition to providing more procedures, physicians at NOHC were more likely to “perform diagnostic coronary angiographies on patients — the

¹⁸⁹ *Id.*

¹⁹⁰ *Id.*

¹⁹¹ To read the statute providing for *qui tam* claims, see 31 U.S.C. § 3730(b) (2012).

¹⁹² *Id.* §§ 3729–3733 (2012).

¹⁹³ See Press Release, U.S. Dep’t of Justice, EMH Regional Medical Center and North Ohio Heart Center to Pay \$4.4 Million to Resolve False Claims Act Allegations (Jan. 4, 2013) [hereinafter EMH Regional Press Release], available at <http://www.justice.gov/usao/ohn/news/2013/04janemh.html>.

¹⁹⁴ *Id.*

¹⁹⁵ *Id.*

¹⁹⁶ See Abelson, *Health Procedure*, *supra* note 186.

¹⁹⁷ It was not until 2011 that a seminal study was released in the *Journal of the American Medical Association* that cast serious doubt on the effectiveness and appropriateness of stents. See Paul S. Chan et al., *Appropriateness of Percutaneous Coronary Intervention*, 306 J. AM. MED. ASS’N 1, 53 (2011) (concluding that only 50% of stents were clearly appropriate for non-acute indications). Bloomberg reported that the American College of Cardiology has since removed the term “inappropriate” from stents’ clinical guidelines, and has replaced it with “rarely appropriate.” Peter Waldman, *Doctors Use Euphemism for \$2.4 Billion in Needless Stents*, BLOOMBERG (Oct. 30, 2013, 9:01 PM PDT), <http://www.bloomberg.com/news/2013-10-30/doctors-use-euphemism-for-2-4-billion-in-needless-stents.html>. About 700,000 coronary stents are placed in the United States annually. *Id.*

primary test that [was] used to detect blockages in the first place.”¹⁹⁸ Further, doctors at NOHC engaged in “staging” — in which the cardiologists would not unblock all affected vessels during one procedure, claiming that “operating on too many vessels during a single procedure” presented “a safety issue.”¹⁹⁹ Others have referred to the technique as “recycling patients” — in which NOHC performed “repeated procedures, including stents, on the same patients.”²⁰⁰

In combatting any indication of misconduct, NOHC president Dr. Shaeffer noted that his doctors “follow[ed] medical guidelines in determining treatments.”²⁰¹ He also stated that “patients with coronary artery disease [were] best served when doctors intervene[d] quickly” — “[w]ith absolutely no exception . . . patients given aggressive treatment will come out with a better outcome,” he said.²⁰² In the summer of 2006, when the *New York Times* published its original story, the DOJ had not begun an investigation, but that quickly changed after Kenny Loughner, a “former manager of EMH’s catheterization and electrophysiology laboratory” filed a *qui tam* complaint in October of that year.²⁰³ Even though the *qui tam* relator Kenny Loughner alleged that “doctors urged nurses and others to falsify complaints of chest pain to justify the unnecessary angioplasties” and “described the doctors’ technique of treating patients in stages, forcing patients to come back for multiple procedures,” the hospital noted that the DOJ did not include the allegations in its findings “and they [were] without merit,” according to NOHC.²⁰⁴

The federal government “alleged that EMH and NOHC performed angioplasty and stent placement procedures on patients who had heart disease but whose blood vessels were not sufficiently occluded to require the particular procedures at issue.”²⁰⁵ For his part, Steven M. Dettelbach, the U.S. Attorney for the Northern District of Ohio, admonished that “[p]atient health and taxpayer dollars have to come

¹⁹⁸ See Abelson, *Health Procedure*, *supra* note 186.

¹⁹⁹ See *id.*

²⁰⁰ Sydney P. Freedberg, *Mother Dies Amid Abuses in \$110 Billion U.S. Stent Assembly Line*, BLOOMBERG (Oct. 10, 2013, 9:01 PM PDT), <http://www.bloomberg.com/news/2013-10-10/mother-dies-amid-abuses-in-110-billion-u-s-stent-assembly-line.html>.

²⁰¹ See Abelson, *Health Procedure*, *supra* note 186.

²⁰² *Id.*

²⁰³ See EMH Regional Press Release, *supra* note 193.

²⁰⁴ Reed Abelson, *U.S. Settles Accusations That Doctors Overtreated*, N.Y. TIMES (Jan. 4, 2013), <http://www.nytimes.com/2013/01/05/business/us-settles-accusations-that-doctors-overtreated.html> [hereinafter *U.S. Settles Accusations*].

²⁰⁵ EMH Regional Press Release, *supra* note 193.

before greed.”²⁰⁶ According to the evidence gathered in the case, NOHC pressured its cardiologists to “refer patients to . . . [the] cath lab,” with one cardiologist noting that he saw “patients with an astonishing number of stents that [he] hadn’t heard before, sometimes exceeding 20 stents.”²⁰⁷

The hospital made public statements following the settlement, with chief executive Dr. Donald Sheldon saying that “no patients, to our knowledge, were ever at risk, and there is no question that the patients treated had heart disease and some degree of blockage.”²⁰⁸ Still, he noted “that the settlement represented ‘a small percentage’ of its cardiology patients who were judged by Medicare to have not had severe-enough medical conditions to justify the procedures performed by North Ohio Heart Center doctors.”²⁰⁹ Interestingly, Sheldon noted that “EMH Healthcare remains committed to providing the most efficient care to patients.”²¹⁰

Dr. Shaeffer posted an official statement in reaction to the settlement to his blog. Noting that the settlement was “not an admission of wrongdoing,” but that NOHC settled “so we can put it behind us and move forward,” Shaeffer made clear that:

It is very important to note that this settlement is *only* about whether or not Medicare covered some procedures we did six to ten years ago that were considered cutting edge at the time. As the physicians on the ground when these decisions were made and the procedures were performed, we felt confident we were making the correct choices for our patients. We still do. . . . As leaders in cardiac care, we have always been early adopters of new technology when we believe using it will help improve our patients’ lives. That was certainly the case when drug-eluting stents were first introduced. We were using the best technology available to take care of a high risk population. We still are. Cardiac care has progressed significantly in just the past few years, as all areas of medicine have. All cardiologists, including our physicians at North Ohio Heart Center, are implanting fewer stents than in the past

²⁰⁶ See *id.*

²⁰⁷ Freedberg, *supra* note 200.

²⁰⁸ Abelson, *U.S. Settles Accusations*, *supra* note 204.

²⁰⁹ Joe Carlson, *Ohio Hospital, Cardiac Group to Pay \$4.4 Million False Claims Settlement*, MODERN HEALTHCARE (Jan. 4, 2013), <http://www.modernhealthcare.com/article/20130104/NEWS/301049951>.

²¹⁰ *Id.*

because delivering optimal medical therapy with lifestyle changes reduces the need for these procedures.²¹¹

Indeed, in response to the allegations, providers at NOHC could argue that the FCA does not explicitly make “aggressive” management of cardiac care illegal,²¹² sure to bring up that it was not clinically evident in 2006, let alone 2001, that aggressive angioplasties and stents were *not* generally helpful to the patients that received them (and, instead, often times, harmful).²¹³ After all, at the time these were performed, providers say they were “cutting edge” procedures.²¹⁴

Still, in an enforcement regime tasked with preventing fraud and abuse in an effort to limit cost growth within Medicare, the markers of the NOHC investigation seem strongly indicative of, at least, health care waste. As the providers at NOHC were administering a procedure at three times the state average and four times the national average, they had a limited ability to argue that all of these procedures were clinically necessary. Unlike the clinical murkiness in the ICD investigation example, the fact that cardiologists exceeded the state and nationwide averages by a large amount was undeniable. To assume that all the NOHC procedures were medically necessary, one would have to conclude that the average physician nationwide failed to place a number of medically necessary stents. Different from the ICD conclusion, cardiologists at NOHC could not argue that the standard applied to them failed to reflect clinical realities; it was composed of comparisons with their peers nationwide and statewide.

²¹¹ *North Ohio Heart Reaches Settlement; Continues to Provide High-Quality Cardiac Care*, N. OHIO HEART, OHIO MED. GRP., PARTNERS FOR YOUR HEALTH BLOG (Jan. 4, 2013), <http://blog.partnersforyourhealth.com/Blog/bid/93734/North-Ohio-Heart-Reaches-Settlement-Continues-to-Provide-High-Quality-Cardiac-Care> [hereinafter *NOHC Blog Post*].

²¹² See 31 U.S.C. § 3729 (2012) (making illegal “knowingly,” “present[ing],” or “us[ing]” a “false or fraudulent claim,” “false record,” or “statement material to a false or fraudulent claim,” among other things). The key argument here would focus on the intent standard under the FCA. If providers could argue that they lacked fraudulent intent, this would be a potential defense to an FCA charge.

²¹³ See Kelly Brewington, *Whether a Stent Is Needed Can Be Tough Call*, BALT. SUN (Jan. 25, 2010), http://articles.baltimoresun.com/2010-01-25/health/bal-md.stents25jan25_1_stents-heart-patients-cardiologists (noting that “for heart patients with few symptoms and less than severe artery blockage, whether to sue a stent is a question with no clear-cut answer, say cardiologists. . . . A recent internal review of heart patients at St. Joseph medical Center in Towson found 369 patients received the coronary implants unnecessarily. Those findings have . . . highlight[ed] a debate among cardiologists and confusion among patients over when stents are necessary”).

²¹⁴ See *NOHC Blog Post*, *supra* note 211.

Thus, the central insight from the regulatory story of NOHC must focus on the fact that it was the *departure from average* over the course of the year (by four magnitudes nationally), rather than a violation of medical necessity, that made their allegations compelling. At the time, the DOJ could not argue that the stents were *not* medically necessary, and, indeed, the cardiologists at NOHC could argue that they felt the stents *were* medically necessary. Given the prevailing medical knowledge in 2003, the NOHC cardiologists' belief may not have been unreasonable — based upon the science itself, it at least was likely not demonstrably fraudulent.

But it was the *cumulative excess* — compared to cardiologists nationwide — that made their stent placements unreasonable. Indeed, it was the excess of the providers of the NOHC that was egregious — the excess added to the power of the allegations, making the case much easier that the cardiologists at NOHC were at least wasteful — and presumably, fraudulent. Viewing the allegations in light of the cumulative excess helps to explain why the NOHC investigation and penalty may feel more justified than the ICD investigation.

IV. A NEW CONSTRUCT OF OVERTREATMENT REGULATION

As currently constituted, linking the overtreatment investigation to the “reasonable and necessary” language of the Medicare statute, or more formally the program’s NCD or LCD determinations, locks the DOJ into conceiving of these overtreatment cases as always featuring medically unnecessary care. And, as a result, the regulation of overtreatment, and the resolution of fraud allegations, is subject to a clinically-based answer; whether the procedure is truly medically necessary or not will determine the outcome of the case. Like the ICD investigation shows, in some instances, the CMS and the DOJ may not be able to get and stay ahead of providers’ clinical innovation and development. Especially for rapidly developing procedures and technologies, the coverage process seems ill-equipped to both govern providers’ behavior and provide reasonable rules for reimbursement. Using a different metric avoids the risk of enforcing an outdated or inaccurate clinical standard.

Further, the NOHC investigation aside,²¹⁵ a substantial amount of the cost and utilization challenge posed in the overtreatment era

²¹⁵ Metrics from the NOHC case — particularly, the comparison between the NOHC cardiologists and the national average — suggested that the cardiologists were administering procedures that were not medically necessary. See Abelson, *Health Procedure*, *supra* note 186 (noting that stents were being placed in Elyria at four times

revolves around care that — when broken down into individually-administered procedures — cannot easily or clearly be called unreasonable or unnecessary. It is care that, when repeated over the course of a year, for instance, becomes cumulatively excessive, but is often in the “grey” of clinical practice. It is the extra x-ray, the inpatient, instead of outpatient, operation, and the extra stent — performed repeatedly. Indeed, it is not unreasonable to assert that, based upon clinical judgment, a particular patient may need a relatively “aggressive” stent placement, but when every patient gets the same “aggressive treatment,” questions justifiably arise.

Through the accumulation of health care services, a pattern of excessive waste or abuse may result. Without such clear evidence of excess — evident, for instance, in the NOHC investigation above — the overtreatment investigation gets bogged down in arguments surrounding what was clinically more appropriate. A new construct for overtreatment would jettison these clinical details for a more straightforward approach.

A. Three Important Characteristics

A new overtreatment construct provides guidance for the DOJ focused on three chief characteristics: (1) cumulative utilization and cost; (2) comparison with similarly-situated peers (importing the standard from the profession); and (3) pre-investigatory notice. These three chief characteristics of the new overtreatment regulatory scheme are explored more deeply below.

1. Cumulative Utilization

From the academy, to Congress, to reimbursement policy, “bundling” has become a buzzword, often mentioned when solutions to Medicare’s cost challenges are discussed. Nicholas Bagley has noted that “Medicare must pay for care in much bigger *bundles*,” and, in fact, pay organizations a “lump-sum” that would then be distributed to providers “to distribute the Medicare payments.”²¹⁶ In 2013, as established by the Patient Protection and Affordable Care Act of 2010 (“ACA”),²¹⁷ CMS announced the “*Bundled Payments for Care Improvement Initiative*,” in which “organizations will enter into

the national average).

²¹⁶ Bagley, *supra* note 42, at 559 (emphasis added).

²¹⁷ See Patient Protection and Affordable Care Act of 2010, Pub. L. No. 111-148, § 3023, 124 Stat. 119, 399 (codified at 42 U.S.C. § 1395cc-4 (2012)).

payment arrangements that include financial and performance accountability for episodes of care.”²¹⁸ Indeed, in some ways, the inpatient prospective payment system (“PPS”) for Medicare Part A reimbursement that relies upon diagnosis-related groups (“DRGs”) to reimburse hospitals for acute care uses bundling to prospectively set rates.²¹⁹ Hospitals are not rewarded for using more — in either number or expense — of any service or product, largely because they will not get paid for it.

Thus, within this new construct of overtreatment regulation, of most importance is that the DOJ’s attorneys use “bundled” data to determine their targets of overtreatment investigations. Using utilization data, outlier providers — after being compared to other similarly-situated providers (both in subspecialty and geographic area) — would be the initial targets of new overtreatment investigations. These investigations would take into consideration the number of patients treated, the number of services rendered, and potentially, the costs of those services. Given the characteristics of the data released in the spring of 2014, this information should be quite illuminating.²²⁰

For the DOJ, delinking the fraud standard from the medical necessity standard — and instead, relying on cumulative utilization of health services — would allow its prosecutors to free themselves from the difficulty of arguing over particular medical services and procedures. In a recent ICD investigation, for example, to deal with the difficulty inherent in regulating providers engaged in clinically complex procedures, the DOJ reached out to a provider association for consultation in constructing proposed settlement arrangements.²²¹ The law — through its enforcers — is simply not equipped with the expertise to determine which providers are engaged in what can be

²¹⁸ *Bundled Payments for Care Improvement (BPCI) Initiative: General Information*, CTRS. FOR MEDICARE & MEDICAID SERVS., <http://innovation.cms.gov/initiatives/bundled-payments/> (last visited July 18, 2014) (emphasis added); see *Fact Sheets: Bundled Payments for Care Improvement Initiative Fact Sheet*, CTRS. FOR MEDICARE & MEDICAID SERVS. (Jan. 30, 2014), <http://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2014-Fact-sheets-items/2014-01-30-2.html>.

²¹⁹ See *Acute Inpatient PPS*, CTRS. FOR MEDICARE & MEDICAID SERVS., <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html> (last modified Aug. 4, 2014).

²²⁰ In terms of liability, it would appear that the FCA may not be the most efficient and accurate tool, and perhaps, a new overtreatment statute should be established — but specific statutory solutions are beyond the scope of this analysis.

²²¹ See Buck, *Enforcement Overdose*, *supra* note 25, at 279-80 (noting the reliance on the Heart Rhythm Society by the DOJ to come up with fair settlement structure to ICD investigation).

called legitimate overtreatment, and those which are clearly illegitimate. A simpler focus on provider-by-provider utilization allows the DOJ to review the amount of services administered, claims filed, and money spent by the federal government — and not a particular patient's blood pressure or artery occlusion percentages. When the harm is overutilization, a provider's cumulative utilization rates, over the course of a year, billed to the Medicare program, can serve as an accurate and defensible proxy for potential investigations and settlements.

It also allows the DOJ to use overtreatment regulation to explicitly and robustly target excess utilization within Medicare. Instead of using it as a regulatory tool meant to enforce Medicare's reimbursement standard, overtreatment regulation would globally seek to prevent providers from administering excessive care to Medicare beneficiaries. A straightforward "bundled" metric of annual utilization per patient could be the first important step toward building a new framework.

2. Comparison with Similarly-Situated Peers

Secondly, for overtreatment regulation to adequately protect provider autonomy, maintain quality of care, and assure that it is pursuing only illegitimate overtreatment, the controlling and applicable standard — for determining the targets of overtreatment investigations — must migrate away from the medical necessity or NCD standard housed within Medicare to the clinical standard of care set by the profession itself. This migration would force the DOJ to determine its targets of overtreatment investigations by *how that provider compares to other similarly-situated peers*, not how that provider compares to Medicare's medical necessity standard or NCD. The development would be positive for both participating providers and Medicare beneficiaries.

As for participating providers, this shift would plant control of the investigatory standard within the profession. Besides giving physicians autonomy in this regulatory framework just because they value autonomy,²²² this allows the foregoing standard of care to govern providers just like it does in the medical malpractice context. Indeed, if it is the case that the profession believes that stents should be placed in a certain percentage of patients — borne out by the numbers of

²²² Indeed, studies have shown providers' willingness to deceive third parties, largely "reinforced by physicians' longstanding and deep-seated commitment toward autonomy in all aspects of professional practice and hostility toward oversight by nonmedical personnel." Hyman, *supra* note 50, at 542.

individuals who receive stents in a given year — then a provider who places stents in a number of patients exceeding that standard by a substantial margin could be deemed a “high utilizer” with comparatively-little controversy. There would be no need to investigate whether providers adhered to a Medicare reimbursement standard because the standard borrowed from within the profession is likely to be highly reflective of clinical realities. And because conflicts between CMS and providers can lead to potentially costly fraud investigations and can affect clinical care,²²³ it is vital that the governing standards accurately reflect clinical reality. The clearest way to ensure the governing standards reflect clinical reality is to link the investigatory standard to the standard of care of practicing providers.

This shift also protects the innovation of providers in individual cases. Allowing the provider community to set the applicable standard allows for the recognition of a various range of acceptable clinical behavior. Given heterogeneity in medical practice, it is surely the case that some providers will diverge from others. Moving the governing standard from a strict NCD to an acceptable range will allow the regulatory regime to avoid targeting potential “false positives” — providers who, because they do not comply with the letter of the NCD, look like they are engaged in fraudulent overtreatment, but who really may be the clinically-important innovators. Indeed, this shift would force the enforcement regime to move away from targeting providers who place ICDs at day thirty-eight instead of day forty, and instead, focus its attention on the providers who place ICDs at a rate that grossly exceeds other similarly-situated providers per patient.

This proposal is nothing new. Others have suggested — as a potential solution to Medicare’s cost crisis — allowing the profession to set a standard of care and for Medicare to link reimbursement with that determination.²²⁴ Although the instant proposal takes no stand on changing Medicare reimbursement policy, others have argued that Medicare should link its repayment structure and the DOJ its investigative enforcement regime to the profession’s determination of what is reasonable or necessary²²⁵ as an effort to address Medicare’s cost challenges.²²⁶ As has been argued, for example, “what counts as a

²²³ See Johnson, *Regulating Physician Behavior*, *supra* note 91, at 1029.

²²⁴ See Muriel R. Gillick, *How Medicare Shapes the Way We Die*, 8 J. HEALTH & BIOMEDICAL L. 27, 37 (2012).

²²⁵ See Tito Fojo & Christine Grady, *How Much Is Life Worth: Cetuximab, Non-Small Cell Lung Cancer, and the \$440 Billion Question*, 101 J. NAT’L CANCER INST. 1044, 1047 (2009).

²²⁶ See Gillick, *supra* note 224, at 37.

benefit in cancer treatment and how much cost should factor into deliberations are not ethical problems that can be relegated to others. No segment of society is better qualified to address these issues than the oncology community.”²²⁷

From the providers’ perspectives, this shift clarifies the rules that govern overtreatment. Instead of basing the investigation on a Medicare NCD or medical necessity determination, cumulative overutilization data are easy to quantify and understand. Conversely, medical necessity determinations are murky in nature²²⁸ and are made all the more complicated by the subjectivity of medical practice.²²⁹ As has been noted, “[p]roviders frequently shoulder the burden of unclear or potentially invalid coverage policy positions in an NCD or LCD.”²³⁰ Eliminating these potentially confusing scenarios would seem to benefit all involved.

Within this new construct, the likelihood of a provider who administered clinically-beneficial care and practiced in an acceptable manner drawing an overtreatment investigation — solely because she failed to administer care in accordance with a reimbursement standard — would likely evaporate. Relatedly, such a framework would allow the medical community to fully engage in a more flexible and organic growth of medical practice without fear of a DOJ investigation. Freeing providers of these concerns would allow them to develop and improve clinical care and to innovate without worry of a DOJ investigation. Nevertheless, if that innovation involves sustained increased utilization, they cannot outpace their peers by a substantial amount.

Finally, patients exposed to this new regulatory framework may expect to experience better clinical care as a result. Besides ultimately seeking to limit the global cost of care by cutting unnecessary services, this new regime would provide a disincentive for the provider to overuse health care services on a particular patient. Indeed, any time a patient is administered care that is unnecessary, she is harmed.²³¹

²²⁷ Fojo & Grady, *supra* note 225, at 1047.

²²⁸ See Brooks E. Allen, Note, *The Price of Reform: Cost-Sharing Proposals for the Medicare Home Health Benefit*, 17 YALE J. ON REG. 137, 164 (2000) (noting that “the medical ‘necessity’ of a given procedure is unclear where the objectives of medical efficacy and cost-effectiveness conflict”); see also Anthony Szczygiel, *Long Term Coverage: The Role of Advocacy*, 44 U. KAN. L. REV. 721, 723 (1996) (calling medical necessity determinations “subjective”).

²²⁹ See Sandra H. Johnson, *Test-Driving “Patient-Centered Health Law,”* 45 WAKE FOREST L. REV. 1475, 1477 (2010) (noting the subjectivity in medical practice).

²³⁰ Blanchard, *supra* note 92, at 615.

²³¹ See Barry R. Furrow, *The Patient Injury Epidemic: Medical Malpractice Litigation*

3. Publicizing Utilization and Cost Data

In the current paradigm, physicians and commentators have referred to health care fraud regulation as a modern-day “speakeasy.”²³² Indeed, authors have equated the regulation of health fraud to a sign that says “No Speeding,” but it does not say what the speed limit is,²³³ and a regulatory structure characterized by irregularity and overuse.²³⁴ Settlement press releases from the DOJ are peppered with similar statements from providers — typically noting that they did not know they were doing anything wrong, that they still believe in the appropriateness of the care they administered, and that they settled simply to avoid the expense of trial.²³⁵

Publicizing the utilization and cost data of each provider, in real time, would remove the potential for surprise when a notice of investigation appears in providers’ mailboxes. Allowing providers to know where they stand in comparison with others would allow them to adjust their behavior accordingly. Just the act of publicizing the data may shame some providers into at least being conscious of the amounts they are costing Medicare. Nevertheless, whether the providers ultimately change their behavior or not, this would give the DOJ backing when providers respond to allegations that “they had no idea” the care they were administering was wasteful or abusive.

Providing notice in this way would allow providers who care to avoid an investigation to change their behavior before full investigatory resources are expended by the DOJ. Conversely, it would illuminate those providers who — even after knowing they are outside of the mainstream of providers — continue to administer overtreatment. This fact, by itself, may suffice to show that the providers were reckless in the administration of care.

B. Regulatory Advantages

Apart from the structural changes, there are regulatory advantages to this new construct of overtreatment regulation. The developments mentioned below feature behavioral self-adjustment by the physician

as a Curative Tool, 4 DREXEL L. REV. 41, 90 (2011) (“These [unnecessary] procedures also expose patients to unnecessary risks because the practice guidelines conclude there is no benefit in such cases. . . . Unnecessary care that lacks therapeutic benefit is presumptively poor quality care.”).

²³² See Hyman, *supra* note 50, at 550.

²³³ Blanchard, *supra* note 92, at 600.

²³⁴ See Buck, *Enforcement Overdose*, *supra* note 25, at 263-64.

²³⁵ See Buck, *Caring Too Much*, *supra* note 23, at 505-07.

at issue, leading to a more efficient regulatory regime. As a result of the shift of overtreatment regulation from medical-necessity-based initiatives to focusing on those providers administering excess care, the DOJ and other regulators would force the medical profession, and specifically, the treating physician, to internalize these utilization-limiting values.

Indeed, up to this point within Medicare reimbursement policy, as well as health care fraud enforcement, it is the failure to force the provider to adjust his or her behavior that has prevented CMS and the DOJ from substantially bending the cost curve. With the number of beneficiaries within the program expected to balloon in the near future, it is evidently clear that the program must look at ways to limit cost growth. Regulatory advantages from the new construct of overtreatment provide enforceable and clear rules without incurring additional regulatory expense.

1. Flexible Persuasion

Due to the use of accumulated data, providers would not have the care associated with every procedure they administered or every patient they treated scrutinized. Within this new regime, providers could still administer additional procedures to patients they *know* need the additional procedures, but doing so to patients too often may cause that provider to be a “high utilizer” over the course of a year. Notably, this pressure would not force a provider to choose less care in any *particular* case — which would allow the solution to steer clear of Medicare’s statutory prohibition to stay out of the practice of medicine.²³⁶ Nevertheless, it may encourage providers — when deciding whether to place the extra stent or administer the combination CT scan, for example — to at least be aware of, and more deliberative about, that decision. Perhaps they would choose less care more often than they currently do. This would force “loose,” not draconian, utilization-conscious decision-making at the bedside.

Such a move would track — and seek to build on and resuscitate — the attempt at cost control through Medicare’s sustainable growth rate (“SGR”) formula.²³⁷ Enacted in 1997, the SGR required that for the amount the reimbursement per patient outpaced the GDP growth, the following year, the reimbursement rate would decrease by that exact

²³⁶ See *supra* note 94 and accompanying text.

²³⁷ See BARRY R. FURROW ET AL., *HEALTH LAW: CASES, MATERIALS AND PROBLEMS* 790 (7th ed. 2013).

amount.²³⁸ Thus based upon the amount providers either overcharged or undercharged Medicare, the following year's reimbursement formula would be affected.

The SGR, however, has never gotten off the ground. Feeling little individual responsibility, physicians have not changed their behavior to avoid the "punishment" of declining rates.²³⁹ Congress has exacerbated the problem by passing a "doc fix" nearly all the years since, undoing the cuts.²⁴⁰ The result has been a widening gulf between what should be the reimbursement rate under the SGR formula and what currently the actual rate is.

Ultimately, the problem with the SGR formula has tracked the age-old tragedy of the commons; the SGR did not impact individuals.²⁴¹ No provider has had a personal stake in the benchmarks that Congress was purportedly requiring providers to meet because no one provider was punished for the collective excess each year that resulted.²⁴² And as Congress repealed the SGR formula year after year, individual providers' fear of negative effects increasingly declined.²⁴³ Reforming the overtreatment regime to (1) clearly publicize the metric the DOJ is using for enforcement, (2) use a standard based on an individual provider's data on utilization, and (3) ensure swift and appropriate enforcement of the standard, seeks to avoid the pitfalls experienced by the SGR framework over the last fifteen years.

²³⁸ See Balanced Budget Act of 1997, Pub. L. No. 105-33, § 4503, 111 Stat. 251, 433 (codified as amended at 42 U.S.C. § 1395w-4(f) (2012)).

²³⁹ Cf. FURROW ET AL., *supra* note 237, at 290 ("[The SGR process ignores] the collective action problem.").

²⁴⁰ See 42 U.S.C. § 1395w-4(f); Mary Agnes Carey, *Congress Is Poised to Change Medicare Payment Policy. What Does That Mean for Patients and Doctors?*, KAISER HEALTH NEWS (Jan. 16, 2014), <http://kaiserhealthnews.org/news/congress-doc-fix-sustainable-growth-rate-sgr-legislation/>; William "Bill" Frist & Steven Schroeder, Op-Ed., *Fix the "Doc Fix" Once and For All*, THE HILL (Sept. 24, 2014, 7:00 AM EDT), <http://thehill.com/opinion/op-ed/218665-fix-the-doc-fix-once-and-for-all> (noting that 2002 was the only year in which the SGR formula was applied without congressional intervention).

²⁴¹ See FURROW ET AL., *supra* note 237, at 290.

²⁴² See Thomas L. Greaney, *Controlling Medicare Costs: Moving Beyond Inept Administered Pricing and Ersatz Competition*, 6 ST. LOUIS U. J. HEALTH L. & POL'Y 229, 237 (2013) ("This approach ignored the patient collective action problem: there was simply no reason for an individual physician to reduce the volume of services based on a net reduction in per service payment levels nationally or even regionally.").

²⁴³ Cf. FURROW ET AL., *supra* note 237, at 290-91 (noting that Congress's "doc fix" has been stymied).

2. Increasing Accuracy

In the current environment, the regulation of overtreatment is subject to prosecutorial discretion, squeezed by the pressures of using investigatory dollars in the right places. This constraint is exacerbated by the inherently subjective nature of the harm at issue and the dependence on clinical expertise of many of the investigations.²⁴⁴ As a result, many overtreatment investigations are an outgrowth of a relator's lawsuit under the FCA. Catching the eye of an Assistant U.S. Attorney, often allegations initially brought in an FCA complaint grow into nationwide initiatives, allowing the DOJ to achieve multiple settlements and make headlines, while basing their initial facts and early allegations on a relator's complaint. But regulating overtreatment in this way opens the regime up to distortion.²⁴⁵

Simply due to the structure and comparative ease of enforceability of the FCA, the DOJ may limit the universe of potential targets when it relies on a relator's complaint to illuminate providers engaged in potential overutilization. Additionally, because some nationwide initiatives may feature cases that are easier to achieve settlement, or because some may grab more headlines, it may not be the case that the "worst actors" are drawing the focus of the government attorneys; reliance on prosecutorial discretion opens up the regime to overenforcement and disorder. As a result, for some current investigations, it may be the case that the providers targeted by an overtreatment-based health care fraud investigation are actually *not* among the most abusive or wasteful for the Medicare program. In this way, the overtreatment enforcement regime appears to be playing out in a counterproductive way.

Instead, linking overtreatment regulation to the actual numbers of utilization for each provider scrubs the framework of any allegation of unevenness. Indeed, those who are the largest outliers — likely those costing the program the most — will be the first targets in a new overtreatment regime. And without question, *all* providers engaged in care that substantially departs from their peers' rates could be targeted with an investigation. This shift evens the playing field, allowing government attorneys to compare utilization to utilization, provider to provider, instead of disparate procedures, harms, and costs. Further, refocusing the regime's targets on those who administer the most procedures per patient per year — instead of those who allegedly administered medical care that was not medically necessary — allows

²⁴⁴ See Buck, *Enforcement Overdose*, *supra* note 25, at 296.

²⁴⁵ See *id.* at 293-94.

the regime to take advantage of the major “regulatory bonus” of “cascaded retreat,”²⁴⁶ which is discussed below.

3. “Cascaded Retreat”

In the new construct, overtreatment regulation could take advantage of a regulatory bonus known as “cascaded retreat,” an enforcement phenomenon that would cost the regulators no additional resources in policing and preventing overutilization. In their seminal work, Professors Margaret Lemos and Alex Stein argue for what they call “strategic enforcement” of a legal regime.²⁴⁷ Under this type of regime, law enforcers focus on the worst violators, “tolera[ting] . . . small-time infringers so long as they stay away from the ‘worst’ category.”²⁴⁸ Importantly, a strategic enforcement mechanism “produces a socially beneficial dynamic — a cascaded retreat from high-end violations — that allows law enforcers to economize on enforcement costs while avoiding the distortions associated with the conventional models.”²⁴⁹ This new model deters individuals from becoming the worst offenders in a legal regime, and due to “self-adjusting comparative identification,” the “crucial” and cheap “cascaded retreat” results.²⁵⁰ This means that because the regulated party is aware that he is an outlier — for instance, a provider who places stents at three times more often than do his peers — he adjusts his behavior to come back toward the average, or standard, of his peers, so as not to stand out to regulators.

In order to illustrate their point, Lemos and Stein provide an example of strategic enforcement in an accessible example: speeding down a highway.²⁵¹ Instead of pulling over every vehicle with a driver that is speeding, police “stop only those cars whose speed is conspicuously above the limit.”²⁵² Those driving down the highway “become motivated not to drive their cars conspicuously fast” because: (1) the drivers do not know what the “conspicuously above” value is in a given context; (2) that criterion “varies from one case to another;”

²⁴⁶ See Margaret H. Lemos & Alex Stein, *Strategic Enforcement*, 95 MINN. L. REV. 9, 18 (2010).

²⁴⁷ See *id.* at 11-13.

²⁴⁸ *Id.* at 18.

²⁴⁹ *Id.*

²⁵⁰ See *id.* at 19.

²⁵¹ See *id.* at 9.

²⁵² *Id.*

and (3) police keep the “criterion unannounced.”²⁵³ This causes speeding drivers to adjust down to the pack. As the authors note, “[t]he benefit from not being an outlier will motivate every driver to slow down. This speed-reduction process will stop at a point at which the driver becomes confident about other drivers’ prevalent speed.”²⁵⁴ Most speeding drivers’ slowdowns will be “significant,” and “[m]ost important, this social benefit will be achieved at an affordable cost.”²⁵⁵ No additional regulators are needed to enforce the speed limit; the rule is effectively internalized by the drivers.

Applying their insight to health care administration and delivery, this new construct of overtreatment regulation would clearly take advantage of the regulatory benefit of “self-adjusting comparative identification,” and “cascaded retreat.”²⁵⁶ Just like the drivers who are speeding in the fastest car on a roadway *know* that they are the driving faster than their peers, under this new regime, outlying providers would be aware that they are outliers. By adjusting the enforcement mechanism so as to target them simply for being excess utilizers, the regime would quite immediately and directly incentivize them to adjust their behavior back to the pack.

Indeed, as it stands now, providers who administer care that is arguably medically necessary have a clinical defense against a health fraud investigation. For example, the cardiologists at NOHC — even a target that outpaced the nationwide average on stent placement by multiples — argued that they were simply “aggressive.”²⁵⁷ Medicare’s recognition of their clinical autonomy forces the regulatory regime to pause, or at least hesitate, pondering the legitimacy of the DOJ’s health fraud investigation. When the metric is based on overutilization, compared to their peer providers, there is no clear clinical defense that exists to muddy the analysis. It may be the case that providers were aggressive or different, but it is also undeniably the case that they are utilization outliers — contributing in a real way to the cost crisis within Medicare.

V. LEGAL AND PRACTICAL DEFENSIBILITY

Notably, this new proposal aligns with guidance recently published by the Office of Inspector General within the Department of Health

²⁵³ *Id.*

²⁵⁴ *Id.*

²⁵⁵ *Id.*

²⁵⁶ *See id.* at 19.

²⁵⁷ *See discussion supra* Part III.B and accompanying notes.

and Human Services (“OIG”).²⁵⁸ Based upon a review of providers responsible for “high cumulative payments,” the recent report envisioned the creation of particular benchmarks; in it, the OIG suggests that providers billing above a certain standard threshold be targeted for automatic bill review by CMS.²⁵⁹ It specifically recommends that “[CMS] establish a cumulative payment threshold — taking into consideration costs and potential program integrity benefits — above which a clinician’s claims would be selected for review and implement a procedure for timely identification and review of clinicians’ claims that exceed the cumulative payment threshold.”²⁶⁰ This conclusion was based upon a review of 303 clinicians who billed more than \$3 million through Medicare Part B.²⁶¹ More than a third (104 in total) were identified as receiving “improper payment,” and a total of \$34 million in overpayments were found.²⁶² In response, CMS “partially concurred” with both recommendations, and noted it would “work with its contractors to research and develop an appropriate cumulative payment threshold that considers costs and potential benefits when determining which claims and providers should be selected for review.”²⁶³

Echoing but expanding the OIG’s suggestions, this proposal’s new construct should shift many of the arguments away from medical necessity, clinical discretion, and scientific debate, and toward utilization totals, cost totals, and comparative research with colleagues. Overtreatment regulation could become one of very few true price controls on the providers’ clinical decision-making within the Medicare program. That the OIG and CMS are already looking into benchmarking suggests that shifting the DOJ’s overtreatment enforcement regime may have support from within the federal agencies tasked with overseeing the Medicare program.

²⁵⁸ See DEP’T OF HEALTH & HUMAN SERVS., OFFICE OF INSPECTOR GEN., A-01-11-00511, REVIEWS OF CLINICIANS ASSOCIATED WITH HIGH CUMULATIVE PAYMENTS COULD IMPROVE MEDICARE PROGRAM INTEGRITY EFFORTS 5 (2013), available at <https://oig.hhs.gov/oas/reports/region1/11100511.pdf>.

²⁵⁹ See *id.*

²⁶⁰ *Id.*

²⁶¹ See *id.* at 3; see also Mike Voorheis, 2 *Wilmington Doctors Likely to Have Medicare Reimbursements Scrutinized*, WILMINGTON STAR NEWS (Apr. 9, 2014), <http://www.starnewsonline.com/article/20140409/ARTICLES/140409641> (noting that four of the twelve providers with the most money received from Medicare locally were ophthalmologists).

²⁶² See DEP’T OF HEALTH & HUMAN SERVS., *supra* note 258, at 3.

²⁶³ *Id.* at 5.

From a general regulatory perspective, Medicare does have power to establish prophylactic rules without running afoul of the Medicare statute. Indeed, HHS's authority to enforce prophylactic rules to ease the administrative burden on the agency has been judicially endorsed.²⁶⁴ By way of example, courts have repeatedly upheld 42 C.F.R. § 413.17, which bars the "reimbursement of presumptively unreasonable costs" — specifically, those between related organizations.²⁶⁵ In barring these payments, the HHS has made a "judgment that the probability of abuse in transactions between related organizations is significant enough that it is more efficient to prevent the opportunity for abuse from arising than it is to try to detect actual incidents of abuse."²⁶⁶ In other words, courts have noted that, "[p]articularly in a program as complex and ripe with potential for abuse as Medicare, the Secretary has broad discretion to control excessive costs by adopting general prophylactic rules which, despite their inherent imprecision, eliminate the need for a cumbersome and expensive process of adjudicating item-by-item the reasonableness of costs."²⁶⁷ Consequently, the likelihood of abusive relationships and resulting excess costs justify HHS taking rather blunt measures. Just like the prophylactic rule barring payment for related agencies, this proposal seeks to end the administrative burden of reviewing and investigating all bills on a claim-by-claim basis while using Medicare's medical necessity or NCD standard; instead, bills incurred from providers who are outliers — again, administering care at substantially higher rates than their peers — could be deemed presumptively unreasonable.

A. *Fraud-Based Legal Theories*

Under this new construct, the enforcement argument shifts. The DOJ's strategy moves from arguing that the federal government paid for something for which it should not have initially paid, to arguing that the federal government was harmed by a cumulative amount of care — based on the number of patients seen or dollars charged — by a particular provider. The misconduct results from the *excess*.

Given prevailing arguments under the FCA, the DOJ would be arguing that cumulative excessive care is "unreasonable" within the

²⁶⁴ See, e.g., *United States v. Estate of Rogers*, No. 1:97CV461, 2001 WL 818160, at *13 (E.D. Tenn. June 28, 2001) (citing judicial support for the prophylactic rule).

²⁶⁵ See *id.*

²⁶⁶ See *Biloxi Reg'l Med. Ctr. v. Bowen*, 835 F.2d 345, 350 (D.C. Cir. 1987).

²⁶⁷ *Marina Mercy Hosp. v. Harris*, 633 F.2d 1301, 1304 (9th Cir. 1980).

meaning of the Medicare statute. Like it does in current cases,²⁶⁸ the DOJ and HHS will be continuing to pursue “unreasonable” care under a new overtreatment construct; government attorneys will simply be arguing that different proof — a substantial divergence between the targeted provider’s utilization rate and that of his similarly-situated peers — demonstrates the “unreasonableness” of the care. In this way, this proposal does nothing to change the underlying legal argument; just like current theory, when the provider or entity certifies that the care administered is “reasonable” on the CMS Form-1500, this certification would be allegedly “false,” based upon this cumulative annual data reflecting clinical patterns.²⁶⁹ In addition to the “false” certification, two additional existing legal theories could provide appropriate housing for the new construct of overtreatment regulation: (1) worthless services theory; and (2) “cost plus” fraud theory. Both are explored below.

1. A New Species of Worthless Services

In the mid-1990s, federal prosecutors devised a bold new theory in an effort to pursue nursing homes that were administering substandard care.²⁷⁰ Recognized in multiple federal courts,²⁷¹ the theory submitted that whenever a clinic or provider billed Medicare for procedures that were grossly substandard, the government was defrauded because it was paying for care that was so substandard it was actually worthless. And by billing Medicare and Medicaid for something that was worthless,

²⁶⁸ See, e.g., DEP’T OF HEALTH & HUMAN SERVS. & DEP’T OF JUSTICE, HEALTH CARE FRAUD AND ABUSE CONTROL PROGRAM ANNUAL REPORT FOR FISCAL YEAR 2013, at 41 (2014), available at <http://oig.hhs.gov/publications/docs/hcfac/FY2013-hcfac.pdf> (noting that a nursing home settled fraud allegations that allegedly “caused the submission of false claims to Medicare and Medicaid for medically unreasonable and unnecessary rehabilitation therapy.” In the case, “unreasonable” describes scenarios in which therapists were “pressured . . . to increase the amount of therapy provided to patients in order to meet targets for Medicare revenue that were set without regard to patients’ individual therapy needs”).

²⁶⁹ As it is not setting reimbursement policy, the *Hays* decision does not prohibit the DOJ from pursuing providers who administer “unreasonable” items or services. See *Hays v. Sebelius*, 589 F.3d 1279, 1281 (D.C. Cir. 2009).

²⁷⁰ See *Buck, Caring Too Much*, *supra* note 23, at 486-87.

²⁷¹ See *United States ex rel. Swan v. Covenant Care, Inc.*, 279 F. Supp. 2d 1212, 1221 (E.D. Cal. 2002) (recognizing worthless services claim, but ultimately denying it); *United States ex rel. Aranda v. Cmty. Psychiatric Ctrs. of Okla., Inc.*, 945 F. Supp. 1485, 1488 (W.D. Okla. 1996) (recognizing wide liability for substandard care).

clinics — particularly nursing homes that were neglecting their patients — were committing health care fraud.²⁷²

This new construct of overtreatment regulation adopts the mantle of the worthless services theory, and extends it slightly. Like the nursing home worthless services cases, the argument here is that when the federal government is billed for services that are worthless — that is, services that are both above and beyond what is required to meet the standard of care and result in no health improvement of beneficiaries — it is defrauded. Using Dempsey as an example, by allegedly administering combination scans to nearly 50% of patients that presented with a chest condition and outpacing the national average of 5%, 45% of the patients who presented to Dempsey received a *worthless* combination scan. Doctrinally, it seems as though there is no difference between a nursing home that administers such substandard care that the care is worthless and a hospital and/or provider that administers clearly excessive procedures that are also clinically worthless. Both cases result in unnecessary loss to the government payer.

2. “Cost Plus” Fraud

A second doctrinal solution focuses on defense procurement fraud. Indeed, the federal government has pursued those engaged in defense procurement fraud (also called “cost plus” fraud) — third parties who enter into agreements with the federal government, most typically the U.S. Department of Defense — to perform services and/or provide items to the government.²⁷³ “Cost plus” fraud occurs when the third party and the federal government are in a “cost plus” contract, defined as a contract in which the government reimburses the third party based upon the amount of costs that the third party incurred in performing the service or manufacturing the item “plus a fee for the contractor’s services and profit.”²⁷⁴ Unsurprisingly, a “cost plus” contract may be “dangerous” for a contracting party.²⁷⁵ Notably, it “provide[s] little incentive for the contractor to control or minimize costs” and one with “a fee based on a percentage of the costs creates an incentive for the contractor to increase costs, thereby increasing the

²⁷² See Buck, *Caring Too Much*, *supra* note 23, at 487-88.

²⁷³ See Randall H. Wintory, *Cost-Plus Contracts: Fair Deal or License to Steal?*, VA. LAW., Oct. 2006, at 34, 34-36, available at http://www.vsb.org/docs/valawyer magazine/wintory_vl1006.pdf; *False Claims Act: Common Types of Fraud — Defense Contractor Fraud*, ALL-ABOUT-QUI-TAM.ORG, http://www.allaboutquitam.org/fca_defense.shtml (last visited July 14, 2014).

²⁷⁴ See Wintory, *supra* note 273, at 34.

²⁷⁵ See *id.*

contractor's profits."²⁷⁶ As such, these contract types are "especially vulnerable to the imposition of illegitimate charges."²⁷⁷

The "cost plus" regime is an apt legal analog to Medicare Part B reimbursement for a number of reasons. Most specifically, participating providers, like contractors in "cost plus" contracts, have a clear incentive to increase costs, and to overuse health care services, as the particular provider's profit increases as the cost to the contracting party (the federal government) increases. Similarly, the Medicare reimbursement framework is susceptible to "illegitimate charges" — and to a substantial amount of fraud, abuse, and unnecessary care.²⁷⁸ Like third-party contractors, providers have little incentive to minimize costs and limit utilization; given the reimbursement framework, they actually have an incentive to increase utilization.

The DOJ has applied the FCA to "cost plus" fraud; specifically, the DOJ has used the FCA to pursue contractors who have allegedly engaged in "cost plus" scams.²⁷⁹ In a recent FCA case, a relator alleged that supervisors ordered employees "to bill time spent on trim pieces for fixed-price contract planes to cost-plus contract planes or to bill for unnecessary trim work."²⁸⁰ Lockheed Martin Corporation, the defendant, then allegedly "submitted these consolidated charges in its bills to the government to hide these practices."²⁸¹ Finally, according to the court, these moves "created the appearance that Lockheed was able to meet its obligations under its fixed-price contracts, while concealing increased profits via fraudulent bills for its "cost plus" contracts."²⁸² The court referred to the fraud as a "padded billing scheme."²⁸³ Denying the defendant's motion to dismiss, the court noted that the relator's allegations "provide detailed factual indicia of

²⁷⁶ *Id.*

²⁷⁷ Robert Bowman, *Companies Are Failing to Detect Financial Fraud in Supply Chains*: Deloitte, FORBES (Apr. 16, 2014, 5:59 PM), <http://www.forbes.com/sites/robertbowman/2014/04/16/companies-are-failing-to-detect-financial-fraud-in-supply-chains-deloitte/>.

²⁷⁸ See Donald M. Berwick & Andrew D. Hackbarth, *Eliminating Waste in US Health Care*, 307 J. AM. MED. ASS'N 1513, 1513 (2012) (documenting the millions lost to wasted care and fraud and abuse in American health care); Cosgrove et al., *supra* note 29, at 5 (noting high incidences of unnecessary medical care in the United States).

²⁷⁹ See, e.g., *United States ex rel. Harris v. Lockheed Martin Corp.*, 905 F. Supp. 2d 1343 (N.D. Ga. 2012) (arguing the FCA applies to "cost plus" fraud).

²⁸⁰ See *id.* at 1347.

²⁸¹ *Id.* at 1348.

²⁸² *Id.*

²⁸³ *Id.*

reliability to plausibly support [relator's] claim that Lockheed knowingly presented false claims for payment to the United States government and false certifications regarding the records that would be material to approval of payment of these false claims.”²⁸⁴

In another case, the contractor had to demonstrate the “reasonability” of its fees to avoid FCA liability.²⁸⁵ Indeed, in “cost plus” contracts, where the “aggregate cost upon the face of the account is so excessive and unreasonable as to suggest gross negligence or fraud, the law would impose upon the contractor the duty of establishing the *bona fides* of his performance of the work.”²⁸⁶ Impliedly, where those fees are unreasonable or deceptive, an FCA action could lie.

Similar to the imposition of the FCA against Lockheed Martin, the argument that the DOJ’s attorneys can employ focuses on the fact that the government was defrauded because it was *overcharged based upon overutilization* of medical care over the course of a year. Parallel to the “cost plus” fraud cases, where the federal government can demonstrate excess and unreasonable utilization that led to excess profits for the participating provider, the FCA should be applicable.

Within this new construct, from the DOJ’s perspective, it should be of no matter whether each artery that received a stent was sufficiently occluded, but instead, it is whether, holistically, over the course of the year, the provider simply placed too many stents that cost the government too much money. Like “cost plus” fraud, if a provider exceeds a comparative benchmark of other similarly-situated providers, it can be said that he has allegedly engaged in a “padded billing scheme” — which would catch the attention of the DOJ, and should draw an overtreatment investigation.

²⁸⁴ *Id.* at 1353-54.

²⁸⁵ *See, e.g.,* United States v. Davis, 803 F. Supp. 830 (S.D.N.Y. 1992), *aff’d in part, rev’d in part sub nom.* United States v. Gen. Dynamics Corp., 19 F.3d 770 (2d Cir. 1994) (analyzing the reasonability of the costs). *But see, e.g.,* United States *ex rel.* Laird v. Lockheed Martin Eng’g & Sci. Servs. Co., 491 F.3d 254 (5th Cir. 2007) (refusing to recognize the applicability of the FCA to a future price bid).

²⁸⁶ *See* Hitt v. Smallwood, 133 S.E. 503, 506 (Va. Spec. Ct. App. 1926) (dismissing a fraud claim based on excess cost because the “law does not and cannot standardize the cost of work”). Indeed, modern reimbursement of Medicare can be differentiated from the facts of the *Hitt* case, as for sure, Medicare has “standardized the cost of the work” — it is simply about overutilization.

B. Practical Details

By using the profession's standard of care, this proposal advocates for an effective importation of some characteristics of the medical malpractice regime — by requiring providers to comply with a profession-based standard or face liability, this proposal pushes fraud enforcement to look a little more like medical malpractice regulation. As a result, a regulatory framework that mirrors the regulation of medical malpractice must be prepared for the critique and challenges the come with that regime. Notes that recognize these challenges, and offered brief solutions, are below.

1. Addressing Clinical Variation

In basing liability on peer behavior, attorneys at the DOJ must be aware of the challenges presented by the “two schools of thought” doctrine in medical malpractice, the nationwide and regional clinical variation between similar providers, and the concern known as “industry capture” in moving toward a peer-based standard. All three challenges are species of how best to handle clinical variation, and all are briefly summarized below.

First, the “two schools of thought” doctrine within medical malpractice litigation “provides an absolute defense . . . when a physician has chosen one medically acceptable course of action over alternative treatments that enjoy the support of other medical experts.”²⁸⁷ In medical malpractice cases, this doctrine — which is also called the “respectable minority” doctrine²⁸⁸ — excuses clinical variation for acceptable administered care. Indeed, in implementing the new overtreatment construct, it is vital that the DOJ not impose liability in an effort to globally homogenize medical care; instead, various and different procedures may be offered, and it is the overutilizers *within* those classes of providers, within a various procedure, that should be the targets of overtreatment investigation. Further, in these overtreatment cases, the allegation focuses on the fact that the provider administering overtreatment is *not* administering an acceptable treatment; indeed, the allegation is that the excess care is not only wasteful, but harmful.

²⁸⁷ Joan P. Dailey, Comment, *The Two Schools of Thought and Informed Consent Doctrines in Pennsylvania: A Model for Integration*, 98 DICK. L. REV. 713, 713 (1994).

²⁸⁸ See Tim Cramm et al., *Ascertaining Customary Care in Malpractice Cases: Asking Those Who Know*, 37 WAKE FOREST L. REV. 699, 704 (2002).

Second, on a related note, a comparative regime must take into account regional variation among providers; indeed, interregional clinical standards can vary substantially.²⁸⁹ Nevertheless, the NOHC, for example, was administering clearly excessive angioplasties — whether compared to cardiologists nationwide or just in Ohio. Again, the prosecutors must take care to account for the real regional differences among various providers and limit their focus to those who substantially exceed the prevailing standard of peer providers in cohesive geographic areas.

Finally, such a new regulatory structure must account for the fact that providers, emboldened to determine the standard of care, may globally adjust upward the amount of care they administer. Accordingly, this new framework does not prevent the DOJ, or CMS for that matter, from setting some sort of range-based standard or limitation as to what is “acceptable.” Providers within a so-called acceptable range, as compared to other providers, would not be targeted for an investigation. Instead of simply trusting the profession that providers are acting in the best interests of their patients and being satisfactory stewards of taxpayer dollars,²⁹⁰ the DOJ can target those providers who compare unfavorably to their peers beyond some acceptable amount, so as not to cede too much regulatory power to the profession.

Indeed, this regulatory strategy would depend on the reasonability of the providers in setting the standard; this assumes that most providers would not attempt to “game” the standard, nor administer unnecessary health care services. Nevertheless, the DOJ could retain

²⁸⁹ See CTR. FOR THE EVALUATIVE CLINICAL SCIS., DARTMOUTH MED. SCH., *THE DARTMOUTH ATLAS OF HEALTH CARE* 1998, at 114 (John E. Wennberg & Megan McAndrew Cooper eds., 1998), available at <http://www.dartmouthatlas.org/downloads/atlas/98Atlas.pdf> (noting that “variation in rates of CABG [coronary artery bypass grafting] across geographic regions suggests that physicians have different symptom ‘thresholds’ for recommending surgery”); see also James F. Blumstein, *The Legal Liability Regime: How Well Is It Doing in Assuring Quality, Accounting for Costs, and Coping with an Evolving Reality in the Healthcare Marketplace?*, 11 *ANNALS HEALTH L.* 125, 136 (2002) (observing “unexplained variations in medical practice across geographic regions”); Jamie Staples King & Benjamin W. Moulton, *Rethinking Informed Consent: The Case for Shared Medical Decision-Making*, 32 *AM. J.L. & MED.* 429, 446 (2006) (noting the “evidence of wide geographic variation in treatment practices and variance between physicians on information disclosure”).

²⁹⁰ This suggestion contemplates the fact that without CMS’s medical necessity standard as a benchmark, all providers would inflate the amount of care they administer, causing the subspecialty-based peer comparison to fail to provide a sufficient check on the billing and utilization patterns of providers.

discretion to impose a “snapshot” range of standards to prevent an inflation of the standard. Additionally, these standards could be linked to the previous year’s rates — with a defined and limited increase allowed — preventing the profession from ballooning the number of procedures administered from year to year. However, in some ways, in an effort to ensure that expertise drives regulation, providers’ standards must control here.

2. Focusing on the Big Utilizers

It is clear that a reordering of the regulatory structure will likely result in a change of the targets of the investigation. Particularly, a more orderly regulatory framework that targets providers who excessively outpace their similarly situated peers will result in the DOJ targeting those engaged in excessive overutilization. And, as a result, the DOJ may not focus its regulatory resources on those engaged in allegations of minor overutilization. Indeed, “cascaded retreat” enforcement specifically envisions this phenomenon.²⁹¹ Minor offenders may evade enforcement.

As providers who are the most excessive outliers adjust downward, however, the hope would be that the DOJ would increasingly target providers whose utilization rates are less and less striking. On its face, that the DOJ will target those with the most egregious overutilization rates could be a positive development for controlling costs and preventing overtreatment; after all, the top ten Medicare billers in 2012 were responsible for \$121 million in annual costs to Medicare.²⁹² When seeking to punish excessive waste in the system, it only makes sense for the DOJ to pursue those most likely responsible.

CONCLUSION

Currently dominated by detail-oriented clinical questions, overtreatment investigations based upon medical necessity and Medicare’s NCDs draw the ire of the clinical community while failing to produce an authoritative and clear message regarding health care fraud and abuse. That the investigation comes down to a clinical marker or characteristic highlights the difficulty government attorneys experience in regulating overtreatment in an era of increased DOJ anti-fraud resources. The regulatory challenges, juxtaposed against the

²⁹¹ See Lemos & Stein, *supra* note 246, at 19.

²⁹² See Millman, *supra* note 123.

direness and immediacy of Medicare's cost crisis, highlight the need for a more efficient, effective, and calibrated regulatory response.

Indeed, American providers who provide too much expensive care are in need of real but reasonable pressure to be mindful of the amount of excessive care they provide. This proposal, which reconceives of overtreatment regulation as pursuing excess utilizers, seeks to avoid many of the drawbacks of the current system while protecting the autonomy of participating providers. It also seeks to provide a path forward amid substantial current threats to the Medicare program in an effort to build a legal regime more accurately aligned with the goals of cost control. And upon implementation, overtreatment regulation may finally provide a long-awaited and substantial counterbalance to providers' incentives to constantly provide more care.

Medicare cannot afford to wait.