Furthering the Fiduciary Metaphor: The Duty of Providers to the Payers of Medicare

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Five years and two near-death experiences later, the Patient Protection and Affordable Care Act of 2010 (ACA) has restructured the delivery of American health care. It has provided coverage to millions of Americans who previously lacked it, outlawed discrimination in the insurance marketplace, and armed patients with consumer-based tools to streamline their care. The ACA has had a positive impact throughout the country. But it can only go so far.

Separate from providing access, the most daunting challenge facing American health care, and Medicare in particular, is how to control expenditures and utilization in an era of unprecedented enrollment growth. Past efforts to control expenditure and utilization have failed, and starkly conflict with the dominant paradigm in American health care that sanctifies the autonomy and nearly unlimited discretion of the American health care provider. This

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paradigm often views attempts that seek cost-effectiveness as heavy-handed government intervention. But as Medicare’s enrollment is likely to swell from 52 million today to nearly 90 million by 2040, the costs and utilization problem will not abate with age. While the ACA may help reduce unnecessary and unwanted care and expand coverage, it cannot fully address the overtreatment problem due to a confluence of factors—namely, the often-acute emergent situations and incomparable pain patients encounter, the imperfect agency relationship between patients and payers, and the intractable information asymmetry that exists within the enterprise.

This challenge begs for creative legal and policy-based solutions that seek to maintain provider autonomy and patients’ freedom of choice, but also construct reasonable incentives and limitations to prod providers and Medicare beneficiaries into choosing more cost-effective treatments. It is made all the more difficult by Medicare’s reimbursement structure, a regime that still largely rewards and incentivizes excess. Recognizing that tension, this piece nods to previous scholarship that has suggested importing fiduciary principles into the provider-patient relationship, but builds on it by arguing for the inculcation of fiduciary principles into the largely unrecognized payer-provider relationship. Requiring the provider to owe a duty of loyalty to the payers in the Medicare enterprise—American taxpayers—would introduce pressures on providers to limit excessive and expensive health care by opening the door for Medicare to seek judicial remedies in cases of wrongdoing. This new duty would further nuance the provider’s loyalties and also reflect other professionals’ multilayered duties of loyalty. Finally, this move would not increase regulations governing providers, nor rob them of their dear autonomy, but would limit unreasonable health care costs and utilization where possible—something that, heretofore, Medicare has failed to do.

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In that moment of terror, I was anything but the well-informed, tough customer with lots of options that a robust free market counts on. I was a puddle.1

–Steven Brill

In a striking piece for Time magazine, journalist Steven Brill—a leading commentator on, and critic of, America’s bloated health care system2—describes his recent open-heart surgery.3 Brill’s article undoubtedly personalizes, from the patient’s perspective, the challenges facing the cost-control effort in American health care4—even though he has been scathing in his critique in other works.5

Arguing that doctors’ and hospitals’ financial incentives6 or patients’ perceived moral hazard7 cause too much unnecessary care is an easy academic

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3. Brill, supra note 1, at 34.
4. Id.
6. See, e.g., Andrew Soergel, Study: Doctors Paid More for Multiple Procedures than for Multiple Patients, U.S. NEWS & WORLD REP. (Dec. 8, 2014), http://www.usnews.com/news/newsgram/articles/2014/12/08/study-doctors-paid-more-for-multiple-procedures-than-for-multiple-patients [http://perma.cc/TY49-JAUID] (noting that critics argue that “doctors have more financial incentive to spend their time ordering potentially unnecessary tests or procedures for a single patient than to efficiently treat an individual and move on”). Further, a 2014 study suggests that even two years after the passage of the ACA’s payment reforms, “the nation’s highest-paid doctors still benefit
exercise. But, as Brill shows, personally facing the fear and uncertainty that confront patients on gurneys adds dimension and complexity to the struggle to solve the uniquely American problem of overtreatment. The uncertainty that faces patient Brill swamps the overtreatment threat that concerns author Brill:

[A]s far as I was concerned, they could have tested my blood 10 times a day if they thought that was best. They could have paid as much as they wanted to that nurse’s aide with the scale or to the woman who flawlessly, without even a sting, took my blood. The doctor who had given me an angiogram the afternoon before the surgery and then came in the following week to check on me became just a nice guy who cared, not someone who might be trying to add on an extra consult bill. Brill’s first-person account illustrates the complicated challenges that even the most well-informed, consumer-savvy patients face when confronted with an emergent health concern. Often patients are helpless and weak, believing in—and dependent on—the heroic goodness of the American provider.

The law, however, is not aligned. When the patient is preoccupied, the patient’s legal and bioethical protections have little force. And the government health care programs have not spent enough regulatory energy on building flexible and common-sense rules that incentivize cost-effectiveness and limit excess. Indeed, the overtreatment threat is particularly acute in Medicare, from a fee-for-service payment model. . . . ‘In Medicare’s fee-for-service system, some physicians are collecting large fees by ordering services munificently.’” Id.

7. Moral hazard is typically defined as the idea “that patients will overutilize health care services unless they pay enough for them.” John P. Geyman, Cost-Sharing Under Consumer-Driven Health Care Will Not Reform U.S. Health Care, 40 J.L. MED. & ETHICS 574, 574 (2012); see also M. Gregg Bloche, The Invention of Health Law, 91 CALIF. L. REV. 247, 252 (2003) (stating that moral hazard is the idea that not having to pay for treatment alters the patient’s treatment preference, but ultimately noting the deficiencies in moral hazard theory as applied to health insurance because it obscures normative questions and lacks same practical appeal as in other insurance contexts). But see Geyman, supra (stating that the moral hazard theory has been “discredited by actual experience over the years”).

At a basic level, moral hazard stands for the idea that “[s]omeone else appears to be paying for it, so who cares how much it costs?” SANDEEP JAUHAR, DOCTORED: THE DISILLUSIONMENT OF AN AMERICAN PHYSICIAN 163 (2014).

8. See Brill, supra note 1, at 38 (“Fear of illness. Or pain. Or death. And wanting to do something, anything, to avoid that for yourself or a loved one . . . . There were occasions during those eight days in the hospital when the non-drug-addled part of my brain wondered, when nurses came in for a blood test twice a day, whether one test was enough and what the chargemaster cost for both was going to look like. But most of the time the other part of my brain took over, the part that remembered my terror during those blackouts and the overriding fear . . . . that lingered in someone whose chest had been sawed open and whose heart had been stopped.”); see also Atul Gawande, Overkill, NEW YORKER (May 11, 2015), http://www.newyorker.com/magazine/2015/05/11/overkill-atul-gawande [http://perma.cc/7EZG-EEWL] (“ Virtually every family in the country . . . has been subject to overtesting and overtreatment in one form or another.”); AMERICANS GET TOO MUCH HEALTHCARE, THEIR DOCS SAY, REUTERS (Sept. 26, 2011), http://www.reuters.com/article/us-too-much-healthcare-idUSTRE7SP5NN20110926 [http://perma.cc/L3DU-NBRY].


10. Id.
which lacks many of the tools that private insurance can use to limit cost and excess, and particularly prevalent in clinical scenarios where multiple treatment options seem reasonable.

But Medicare is not just a neutral party in the fight against overtreatment; Medicare has actually played a role in causing overtreatment in the first place. The nature of the health care enterprise and its reimbursement mechanism directly enable the provider to recommend and steer the patient to the more expensive, complex, and aggressive treatment. Even though Medicare’s reimbursement rules may be “extensive,” the fundamental nature of health care payment still favors the provider—as it always has. The provider enjoys the autonomy to recommend a treatment plan and receive reimbursements for procedures and drugs without explicit reference to costs. Further, although it has shifted rapidly in recent years, the chief reimbursement mechanism still pays physicians based on the volume of the

11. See Isaac D. Buck, Breaking the Fever: A New Construct for Regulating Overtreatment, 48 U.C. DAVIS L. REV. 1261, 1270–82 (2015) (discussing structural and policy-based barriers that prevent Medicare from incorporating cost-effectiveness). This is particularly the case in the context of paying for and approving new drugs. Id.


The financial structure of medical care also accelerates costs. Doctors and hospitals commonly charge fees for services. The more services, the more fees; the higher the fees, the higher the income. Doctors decide what patients need. But perhaps costs were justified by the quality of care? Alas, doctors were presumptively the only qualified judges, and the profession systematically refused to discuss or divulge quality concerns to nonphysicians.

Id. (internal quotation marks omitted).


services they provide. The two parties in the room—the patient and the provider—have little incentive to limit costs and utilization solely for the good of the Medicare program.

With preoccupied, pained patients and providers inadequately pressured to be cost-effective, no party to the clinical relationship is incentivized to limit utilization. The one party who would be likely to push for limits on utilization and cost is the payer—in Medicare, the American taxpayerv. Nevertheless, the payer is an unrecognized participant in the health care delivery system and, legally, the payer in the Medicare program is almost a nonparty. Unlike in other buyer-seller scenarios, the payer for services for Medicare beneficiaries has been startlingly unable to influence the participating provider. As a result, providers’ influence over payers has begun to parallel the so-called monopolistic power that providers enjoy over their patients. Extensive

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17. The trend is away from solely volume-based reimbursement, however. See Better Care. Smarter Spending. Healthier People: Paying Providers for Value, Not Volume, CTRS. FOR MEDICARE & MEDICAID SERVS. (Jan. 26, 2015), http://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2015-Fact-sheets-items/2015-01-26-3.html [http://perma.cc/WC3S-973R] (noting that in 2014, “an estimated 20 percent of Medicare reimbursements had shifted to [alternative payment models],” and that by 2016, the goal is 30 percent). Nevertheless, even some alternative payment models still incorporate volume. See JAUHAR, supra note 7, at 101 (“Under [Pay for Performance], there is pressure to treat even when the diagnosis isn’t firm.”). And the drug reimbursement structure still provides an incentive to order more expensive drugs. See discussion and accompanying notes, infra Part I.

18. In fact, providers not only lack any incentive to limit costs, they actually have an incentive to increase costs. See JAUHAR, supra note 7, at 228 (“As is so often the case in our health care system, doctors’ incentives do not serve broader social goals. This virtually guarantees that proposed reforms like cutting readmissions, reducing unnecessary testing, and adopting computerized medical records will fail. . . . Our system, structured to encourage overutilization, needs to provide some inducements to reduce the amount of health care, too.”); Russell Korobkin, Comparative Effectiveness Research as Choice Architecture: The Behavioral Law and Economics Solution to the Health Care Cost Crisis, 112 MICH. L. REV. 523, 541 (2014) (noting that providers face an “even worse” moral hazard problem in that “whereas patients have the private incentive to demand all tests and treatments with a positive expected value net of nonfinancial costs, providers have a profit incentive to recommend even tests and treatments that have a negative expected value to the patient”). Patients, however, may have some incentive to limit costs. See Medicare 2016 Costs at a Glance, MEDICARE.GOV, https://www.medicare.gov/about-medicare-costs/costs-at-a-glance/costs-at-glance.html [http://perma.cc/WRN3-3Q7K] (last visited Jan. 26, 2016) (noting the coinsurance and deductible amounts beneficiaries are required to satisfy for care covered by Medicare in 2016).


20. See Mark A. Hall and Carl E. Schneider, Patients as Consumers: Courts, Contracts, and the New Medical Marketplace, 106 Mich. L. Rev. 643, 652 (2008) (“Not only can illness cripple the patient as seeker of information and maker of decisions, but the sick must engage with doctors in ways that unfit them for the market. Patients rely so much on their doctors that their purchasing choices are severely constricted, so constricted that it is hardly too much to say that doctors wield something like monopoly power over patients.”).
academic thought has been devoted to the correct characterization of the patient-provider relationship, but scholars have paid little attention to the provider-payer relationship, at least when the payer is the federal government and the insurance program is Medicare.

This Article draws on the central tenets of fiduciary law and seeks to apply them to the payer-provider relationship to better protect the fiscal health of the Medicare program. In some ways, this analysis builds on and extends the argument espoused by Professor Maxwell Mehlman in pushing for the fiduciary metaphor’s application to the doctor-patient relationship. Of course, this proposal is different in kind. This Article extends the argument to the government payer of those health services contending that the provider should not only have a fiduciary duty to each patient, but also a fiduciary duty to the party footing the bill, at least for the Medicare program with its unique financing structure.

21. One of the more recent developments in academic thinking on the patient-provider relationship has been the inculcation and recognition of the fiduciary paradigm in the clinical setting. Academics have argued that the provider-patient relationship is a fiduciary relationship, and thus subject to the protections of fiduciary law that safeguard the trust so necessary to a healing clinical relationship. See Mark A. Hall, Law, Medicine, and Trust, 55 STAN. L. REV. 463, 477-82 (2002) (highlighting trust’s many values in the patient-provider relationship, including how patient trust may even impact a given treatment plan’s effectiveness); David H. Thom et al., Measuring Patients’ Trust in Physicians When Assessing Quality of Care, 23 HEALTH AFF. 124, 125 (2004) (noting that “[t]rust is widely recognized as being central to the doctor-patient relationship”). In some ways, these conclusions are rather unsurprising; it is unsurprising that the provider must be a loyal and trustworthy fiduciary to each patient they treat. Perhaps some patients assume that the doctor-patient relationship has always contained this explicit guarantee. See id.

22. Recent proposals have included creative ideas for incorporating the fiduciary relationship into the provider-patient enterprise. See Anna B. Laakmann, When Should Physicians Be Liable for Innovation?, 36 CARDozo L. REV. 913 (2015) (arguing for a “fiduciary framework” to police physicians who innovate, with a particular focus on the decision-making process and not on the substance of the ultimate clinical decision).

While Medicare’s payment policies have modernized under the Patient Protection and Affordable Care Act of 2010 (ACA), the importation of fiduciary principles into the legal relationship between the provider and payer would further minimize the volume-based incentives that still push providers to constantly provide more treatment. This paradigmatic solution would be broader than imposing new alternative payment techniques on Medicare providers—particularly when it comes to other health care treatment decisions where providers continue to enjoy nearly unchecked discretion, even under the new reimbursement regimes.

No matter the reimbursement regime, enterprising doctors will find ways to increase profits. Application of fiduciary principles fits classically here because—like in the corporate context—the provider has a personal financial incentive that could conflict with the financial interests of the public payers. Like when applied to a corporate board of directors, fiduciary law can counteract the Medicare provider’s profit motive. And like shareholders in a corporation, Medicare’s payers need additional protection.

Finally, recognition of a payer-provider fiduciary relationship would enrich the provider’s duties of loyalty and align legal protections with the reality of health care delivery in modern America. The provider’s primary duty of loyalty would remain to the patient, but this shift would enable Medicare to influence the provider to, where possible, avoid recommending treatment options that may be futile, unnecessary, and overly expensive when compared to clinically acceptable alternatives. This analysis recognizes that, like lawyers, providers have nuanced and multiple professional duties. Given Medicare’s financial challenges, viewing the provider’s loyalties as belonging to a singular constituent is outdated and impractical in America’s modern health care enterprise.

25. See discussion and accompanying notes, infra Part I; see also William Shrank et al., Correcting the Blind Spot in Accountability: The Role of Pharmacy Care, HEALTH AFF. BLOG (June 25, 2014), http://healthaffairs.org/blog/2014/06/25/correcting-the-blind-spot-in-accountability-the-role-of-pharmacy-care [http://perma.cc/YE33-Y9SS] (“In addition, bundled payments and patient-centered medical home programs target hospitals and primary care providers to promote higher quality and lower cost care. All these programs have largely excluded prescription drug costs in their calculus, and offer no direct incentives for Part D plans to participate in and improve care.”).

As of summer 2015, many providers taking advantage of the new coordinated care model of accountable care organizations (ACOs)—one of the many ACA tools that seeks to improve cost-effectiveness—“had no meaningful incentive to promote cost-effective medication use,” although that may be changing. Shrank, supra. The Centers for Medicare and Medicaid Services (CMS) have indicated an interest in increasing coordination between pharmaceutical companies and ACOs. Id. In late June 2014, CVS Caremark announced a partnership with seven ACOs in California, New Jersey, and Florida. See Zacks Equity Research, CVS Forms Pharmacy Care Alliance, NASDAQ (June 30, 2014), http://www.nasdaq.com/article/cvs-forms-pharmacy-care-alliance-analyst-blog-cm366537 [http://perma.cc/M4DJ-L3W5].
26. See JAUHAR, supra note 7, at 96–97.
This Article proceeds in four parts. Part I introduces the overtreatment threat and presents a prominent recent example of the lack of regulation of overtreatment and excess costs. Part II summarizes the current attempt to empower patients, with a focus on consumer-based tools. Part III highlights general fiduciary analysis principles to set the stage for the application of those principles to the payer-provider relationship. And finally, Part IV presents a new fiduciary analysis applied to the provider-payer relationship to rein in American overtreatment and overutilization. Further, Part IV summarizes the policy reasons that support importation of the fiduciary duty into this vital but infrequently addressed relationship.

I. THE CHALLENGE OF EXCESS

Given the state of the patient at the “gurney moment,” reining in the majority of American healthcare excess is dependent on influencing the provider. This entails mixing the appropriate amount of controls with the right number of incentives for the Medicare provider, the expert actor who coordinates and suggests the scans, procedures, pills, and surgeries that cost the American taxpayer hundreds of billions of dollars—in 2014, $505 billion.27 But it is difficult for any cost-conscious regime to battle the incentives baked into the Medicare reimbursement framework, which lead providers to administer extra tests and procedures, as well as more expensive devices and drugs.28 And because the mind of the patient—like Steven Brill—is often elsewhere, counting on the typical Medicare beneficiary to push the doctor into administering “less” or cheaper health care is unlikely to succeed in many clinical circumstances. Unsurprisingly, the patient remains largely powerless to prevent unnecessary care and utilization.29

Adding to the challenge, overtreatment—a chief driver of financial waste in American health care—has many causes and species. Overtreatment may include care that is not medically necessary; care that is necessary, but inefficient; and “discretionary care of questionable value,”30 or what Atul

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27. The Facts on Medicare Spending and Financing, supra note 19. This was the total figure for Medicare outlays in 2014, which includes an offset in the expenditures for collected premiums and other payments; Medicare’s benefit payments totaled $597 billion in 2014.
28. See discussion and accompanying notes, infra Part I.A.
Gawande calls “no-value care.”31 Other causes of medical waste, like fraud and abuse and excessive administrative costs, are often also included under the overtreatment umbrella.32

As a result, overtreatment is both a market reality and the result of a clinical decision. In other words, medical care might just be too expensive33 or a physician may administer a procedure or drug that is not as cost-effective as a clinically acceptable alternative (or even a therapeutic equivalent). Overtreatment may also occur in scenarios that have nothing to do with either the price of care or the clinical decision-making of the provider. These cases feature excessive administrative costs, wherein the health care entity’s lack of care coordination costs the system more. Finally, another complication to the analysis is that many care-delivery episodes do not fit squarely within one type of overtreatment or another—instead, they are amalgams of different species.34

Additionally, whether a given treatment is overtreatment depends on the individuality of each patient. A procedure may be medically necessary for a particular patient, but inefficient as compared to a reasonable alternative. That same procedure may not be medically necessary when performed on a different patient. Finally, on a third patient, the procedure may both be necessary and the most efficient clinical option.

It is easy to see that policing this kind of activity by differentiating the necessary from the unnecessary, the efficient from the inefficient, and maybe even the fraudulent from the legitimate poses a complex challenge for Medicare. Particularly in situations where multiple clinical options seem reasonable, the “grey” cases in which clinically minute details separate the appropriate from the inappropriate—the dark corner within American health care where overtreatment and excessive utilization thrives—are the most difficult to detect and deter.

Each of these species of overtreatment may require its own legal and policy-based solution. What follows is an example of one type of overtreatment—what Professor Jessica Mantel has called inefficient care, or “tests and treatments that are more costly than alternatives of similar therapeutic value.”35 In cases like these, providers make the common-sense

32. See Isaac D. Buck, Enforcement Overdose: Health Care Fraud Regulation in an Era of Overcriminalization and Overtreatment, 74 Md. L. Rev. 259, 275 (2015); see also Mantel, supra note 30, at 123 n.7.
34. Whether or not a procedure is necessary but inefficient, or wholly unnecessary, is muddied by the realities of clinical variation and expert disagreement. See Buck, supra note 32, at 305–06 (relating how investigated providers can claim their care was simply more aggressive than others).
35. See Mantel, supra note 30, at 124.
argument that they are the clinical expert party and are in the best position to
determine what procedures and drugs have the best therapeutic value.
Nevertheless, with a Medicare program facing decades of exploding
enrollment, these scenarios present stark reminders of the shortcomings of
current regulation and the need for a reasonable but robust solution.

A. An Expensive Blind Spot

Age-related macular degeneration (AMD)\textsuperscript{36} is a “common eye condition”
that causes damage “to the macula, a small spot near the center of the retina
and part of the eye needed for sharp, central vision.”\textsuperscript{37} As it progresses, AMD
causes an increasingly blurry area to form “near the center of vision,” which
may grow larger or cause “blank spots,” and ultimately results in loss of
eyesight.\textsuperscript{38} The leading cause of blindness in older Americans,\textsuperscript{39} AMD
particularly affects the most elderly—as many as 22 percent of Americans
older than eighty-five live with the condition.\textsuperscript{40}

Further, as many as fifteen million Americans are currently living with the
condition.\textsuperscript{41} With an increasing elderly population, that number is expected to
grow.\textsuperscript{42} Diagnosed cases of AMD increased from 1.7 million in 2000 to nearly
2.1 million in 2010.\textsuperscript{43} The number of new AMD cases in 2030 is projected to
top 3.5 million, with more than 5 million Americans expected to be diagnosed

\begin{thebibliography}{99}
\bibitem{38} Id.
\bibitem{42} See CTRS. FOR DISEASE CONTROL & PREVENTION, THE STATE OF AGING AND HEALTH IN AMERICA 2013 ii (2013), http://www.cdc.gov/features/agingandhealth/state_of_aging_and_health_in_america_2013.pdf [http://perma.cc/FZ8P-QSEXK] (noting recent growth in the number and proportion of older adults is unprecedented in U.S. history). Two factors—longer life spans and aging baby boomers—will combine to double the population of Americans aged sixty-five or older during the next twenty-five years to about seventy-two million. By 2030, these older adults will account for roughly 20 percent of the U.S. population. Id.
\end{thebibliography}
Two drugs, Lucentis and Avastin, are used to treat AMD. Genentech, a wholly owned subsidiary of the Roche Group, manufactures both. Even though Lucentis has been approved by the Food and Drug Administration (FDA) to treat AMD and Avastin has not—leaving it completely reliant on physicians’ off-label usage—numerous recent studies have concluded that the two drugs are equally effective, with one calling them “virtually identical.” Both are highly successful in treating AMD and one principal investigator of a year clinical trial to compare how well the two drugs worked—“early AMD is diagnosed by the presence of medium-sized drusen”).


In a first-of-its-kind study in 2011, the National Institutes of Health (NIH) undertook a two-year clinical trial to compare how well the two drugs worked in treating AMD. See Avastin and Lucentis Are Equivalent in Treating Age-Related Macular Degeneration, supra. The results indicated that the treatments “had equivalent effects on visual acuity when administered according to the same schedule.” CATT Res. Grp., Ranibizumab and Bevacizumab for Neovascular Age-Related Macular Degeneration, 364 N. ENG. J. MED. 1897, 1897 (2011). The improvements for patients using either drug were “virtually identical (within one letter difference on an eye chart).” N5CR] (presenting that “[e]arly AMD is diagnosed by the presence of medium-sized drusen”).

54. Id.; see John E. Osborn, Can I Tell You the Truth? A Comparative Perspective on Regulating Off-Label Scientific and Medical Information, 10 YALE J. HEALTH POL’Y, L., & ETHICS 299, 336–38 (2010) (“Genentech was at the very least in a terribly awkward position during the period 2004 to 2007 as interest in off-label use of Avastin intensified.”).

55. NIH Study Finds Avastin and Lucentis Are Equally Effective in Treating Age-Related Macular Degeneration, supra. See also John Geyer, Cancer Drug Avastin May Be Cheap Solution for Macular Degeneration, supra. The improvements for patients using either drug were “virtually identical (within one letter difference on an eye chart).” N5CR] (presenting that “[e]arly AMD is diagnosed by the presence of medium-sized drusen”).

56. Id.; see John E. Osborn, Can I Tell You the Truth? A Comparative Perspective on Regulating Off-Label Scientific and Medical Information, 10 YALE J. HEALTH POL’Y, L., & ETHICS 299, 336–38 (2010) (“Genentech was at the very least in a terribly awkward position during the period 2004 to 2007 as interest in off-label use of Avastin intensified.”).

57. NIH Study Finds Avastin and Lucentis Are Equally Effective in Treating Age-Related Macular Degeneration, supra.
recent study even said, “The dramatic and lasting improvement in vision with these two drugs is extraordinary.”\(^{50}\)

As AMD affects a number of elderly Americans, Medicare covers both of the drugs with few restrictions. Indeed, America’s “crown jewel”\(^{51}\) public insurance program is Lucentis’s “largest single customer.”\(^{52}\) Together, Lucentis and Avastin accounted for “one sixth[] of the Medicare Part B drug spending in 2010.”\(^{53}\)

Even though the production costs for each drug are similar,\(^{54}\) the costs charged per injection are radically different: Avastin costs $50 per injection and Lucentis costs about $2,000 per injection.\(^{55}\) As a result, the “annual maximum cost of treating a patient with Avastin is $650, and the annual cost of treatment with Lucentis is $50,000.”\(^{56}\) According to a 2012 report by the inspector general of the U.S. Department of Health and Human Services (HHS), “[T]he final cost of a dose of Avastin is about 1 percent the cost of a dose of Lucentis, on average ($26 vs. $1,928).”\(^{57}\) And Lucentis constituted “nearly 10% of the entire Medicare part B drug budget” in 2010.\(^{58}\)

50. See NIH Study Finds Avastin and Lucentis Are Equivalent in Treating Age-Related Macular Degeneration, supra note 49. Rates of serious adverse events—“such as stroke, heart attack and death”—were “similar for patients who received either drug.” Two-Year Results Confirm Strong Efficacy of Two Drugs in Treatment of Age-Related Macular Degeneration, YAHOO FIN. (May 2, 2012), http://finance.yahoo.com/news/two-results-confirm-strong-effficacy-113000348.html [http://perma.cc/F3C3-QKVF] (last visited Apr. 6, 2016). Even though serious adverse events occurred in 40 percent of participants on Avastin and 32 percent of participants on Lucentis, the events for those on Avastin “were distributed across many different conditions,” and “[f]ewer doses were associated with a higher rate of [serious adverse events],” which was “not a typical dose-response relationship.” See Avastin and Lucentis Are Equivalent in Treating Age-Related Macular Degeneration, supra note 49. Finally, the number of adverse events was “low and similar for both drugs during the study,” and the researchers were “not capable of determining whether there [was] an association between a particular adverse event and treatment.” Id.


52. Diedtra Henderson, Switch From Lucentis to Avastin Could Save Medicare $18B, MEDSCAPE MED. NEWS (June 17, 2014), http://www.medscape.com/viewarticle/826911 [http://perma.cc/5KQ8-X0RF] (“Medicare could slash $18 billion in spending over the course of 10 years if physicians treated patients with . . . Avastin instead of . . . Lucentis.”). Medicare Part B covers all physician services, while Medicare Part A is responsible for coverage of inpatient treatment. See P.M. Danzon, Pricing and Reimbursement of Biopharmaceuticals and Medical Devices in the USA, 3 ENCYCLOPEDIA HEALTH ECON. 127, 128–29 (2014). The two drugs are reimbursed through Part B because they are administered on an outpatient basis, often in the physicians’ offices. Id.

53. Henderson, supra note 53.

54. Id.

55. Id.

56. Jahnke, supra note 47.

This results in no small expense. According to The Washington Post, "Doctors choose the more expensive drug more than half a million times every year, a choice that costs the Medicare program . . . an extra $1 billion or more annually." Another report has soberly noted that Medicare would save as much as $1.4 billion annually if providers switched from Lucentis to Avastin.

That Lucentis is more expensive obviously makes it more profitable for Genentech—but also more profitable for participating Medicare physicians who prescribe it.1 When physicians use the drugs in their offices, Medicare Part B currently reimburses them for the average price of the drug plus 6 percent.42 Thanks to this reimbursement formula,43 for each dosage of Lucentis administered, the physician’s profit from Medicare is $120; for Avastin, it is slightly more than $3.44

In March 2016, the Centers for Medicare and Medicaid Services (CMS) announced a proposed rule to change the reimbursement structure under Medicare Part B and test different alternative payment policies over five years.45 One such alternative is a reimbursement scheme that would pay the physician the average sales price plus 2.5 percent, in addition to a “flat fee

clinical issues regarding Lucentis and Avastin . . . as well as the implications of the wide variance in cost on the program and beneficiaries”.

58. Daniel F. Martin et al., Ranibizumab and Bevacizumab for Treatment of Neovascular Age-Related Macular Degeneration: 2-Year Results, 119 OPHTHALMOLOGY 1388, 1397 (2012).
59. Whoriskey & Keating, supra note 39; see also Jahnke, supra note 47.
61. Whoriskey & Keating, supra note 39 (noting that Genetech “reaps far more profit when it sells [Lucentis]”).
payment of $16.80 per drug per day.” These proposed reimbursement policies, which will likely take years to test, have already faced harsh criticism. And despite the reduced percentage awarded to the physicians in the new CMS proposal, blunted incentives to prescribe the more expensive Lucentis over Avastin may remain.

Indeed, in an effort to increase use of Lucentis, Genentech began a volume-based rebate program in 2010, where “medical practices [could] earn up to tens of thousands of dollars in rebates each quarter if they use[d] a lot of Lucentis and if their usage increase[d] from the previous quarter.” Nevertheless, The Washington Post reported in 2014 that “U.S. doctors have been using Avastin in about 56 percent” of cases, and about 61 percent of doctors reported to a recent American Society of Retinal Specialists survey that they preferred Avastin for macular degeneration. Under the American Medical Association (AMA) Code of Medical Ethics, it is unethical for a provider to prescribe a drug “for the physician’s financial benefit.”

Genentech argues that Lucentis is “the most appropriate medicine” for treating AMD, and has also reportedly pointed out that Avastin is more dangerous than Lucentis. Bizarrely, Genentech reportedly aimed to discourage Avastin use for safety reasons because the drug “was not approved by the FDA for use in the eye.” These claims, however, seem unsupported. According to the American Medical Association (AMA) Code of Medical Ethics, it is unethical for a provider to prescribe a drug “for the physician’s financial benefit.”

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66. CMS Proposes to Test New Medicare Part B Prescription Drug Models to Improve Quality of Care and Deliver Better Value for Medicare Beneficiaries, supra note 65.
67. See id.
69. Presumably, under the new CMS proposal, a physician’s payment per day and per administration of Lucentis would be $66.80 (2.5 percent of average sales price plus $16.80) instead of $120. For Avastin, it would be $18.05 (same calculation).
70. See Pollack, supra note 62.
71. See Whoriskey & Keating, supra note 39.
72. Id.
74. See Whoriskey & Keating, supra note 39.
75. Id.
76. Id.
77. Id. (“[I]ndependent scientists say such worries are unsupported by the six trials that have been conducted.”).
78. Id.; see also Fiona Godlee, Avastin Versus Lucentis, BMJ (May 2, 2012), http://www.bmj.com/content/344/bmj.e3162 [http://perma.cc/8YUW-D72H] (“Despite evidence that
The costs difference has a real impact on the budget for Medicare Part B. As noted:

CMS will spend $20 billion and patients will spend $5 billion on bevacizumab [Avastin] and ranibizumab [Lucentis] over the next decade. If all patients immediately switched to bevacizumab and continued using it over the ten-year period, CMS spending on these drugs would drop to about $2 billion (savings, $18 billion) over the decade-long period, and patients would spend $420 million (savings, nearly $5 billion).  

Nevertheless, to this point, “Medicare has been powerless to do anything but pay up” for Lucentis. Completely “forbidden from restricting payment to the amount of the less costly alternative,” and perhaps complicit in creating the environment for drug price inflation, Medicare has faced calls by health policy experts for the program to either increase the reimbursement amount for Avastin or simply switch the coverage determination to only cover Avastin. Recently proposed changes may not fully solve the problem. 

The Department of Justice (DOJ) also appears unable to offer comprehensive solutions to the overtreatment challenge. Because regulators cannot argue that administration of Lucentis is medically unnecessary, they are largely stymied from bringing overtreatment-based health care fraud investigations. Overly expensive clinical decisions that target the patient’s

it works in macular degeneration, the manufacturers and marketers (Roche in the US, Novartis in the UK and elsewhere) are actively discouraging its use for this condition, even going so far as taking legal action to prevent such off-label use... Because they want people to use their other drug, ranibuzimab, which is licensed for treating macular degeneration.

80. See Whoriskey & Keating, supra note 39.
81. Id.
82. See Danzon, supra note 53, at 131 (showing that the “ASP + 6% reimbursement rule creates perverse incentives for manufacturers to compete by charging high rather than low prices, because a higher price offers a larger margin to the dispensing physician,” and noting that these incentives “have probably contributed to higher prices for oncologics and other biologics in the U.S.”).
83. Indeed, because Medicare requires care to be “reasonable and necessary,” but requires no cost-effectiveness metric, when a provider seeks reimbursement for the administration of overly expensive drugs, no false statement is made to the federal government. See 42 U.S.C. § 1395y(a) (2012) (“No payment may be made under part A or part B of this subchapter 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... “); Fox, supra note 15, at 50 (suggesting that regulators be “empowered” and “compelled” to consider cost effectiveness when determining coverage policy); Health Insurance Claim Form, CTRS. FOR MEDICARE & MEDICAID SERVS., http://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/downloads/CMS1500805.pdf [http://perma.cc/6356-F6XW] (last visited July 13, 2015) (“I certify that the services shown on this form were medically indicated and necessary for the health of the patient...”); see also Medicare Billing: 837P and Form CMS-1500, DEP’T. HEALTH & HUMAN SERVS. (Oct. 2014), http://www.cms.gov/outreach-and-education/medicare-learning-network-mln/mlnproducts/downloads/837p-cms-1500.pdf [http://perma.cc/49Z4-6LET] (noting that “Medicare payment requires that an item or service... is reasonable and necessary”).
84. See text and accompanying note, supra note 68.
medical needs do not, by their nature, constitute actionable fraud because the decisions cannot be alleged to lack medical necessity. Indeed, because participating providers exclusively decide which drugs are appropriate for their patients, the DOJ cannot argue that these highly expensive clinical decisions are illegal, or even abusive.

But the use of Lucentis certainly seems wasteful and highlights CMS’s inability to adequately police clinical decisions that impact Medicare’s costs. The program allows providers the freedom to choose the drug to prescribe—while simultaneously paying the providers multiples more for one of the two drugs. In short, the Lucentis-Avastin story is one without any legal answer, and one that illustrates the inadequate tools that currently govern health care delivery. The story calls for a paradigm shift in American medicine that seeks not only to increase the funds used to fight fraud, but also to refine those tools so that they are more flexible and targeted.

II.
THE ILL-FITTING CONSUMER-BASED REGIME

As Mark Hall and Carl Schneider presciently argued, American patients are not good consumers. Even though the terrain-shifting ACA seems to build on the assumption that consumer-based protections are good for patients, the relationship between patients and providers is unlike a pure buyer-seller transaction. Consumer tools may help, but there are too many individually

85. See Hutton, supra note 79; see also Henderson, supra note 53.
86. Hall & Schneider, supra note 20, at 659 (“We have seen that across the board patients are ill equipped and badly positioned to purchase medical care well. So extreme are these disabilities that patients must often be wonderfully fortunate even to ascertain the most basic kind of market information—price. Patients, then, will rarely know enough to be successful consumers and will normally follow their doctors’ counsel in making medical purchases.”); see also Schneider & Hall, supra note 14, at 11 (extensively documenting the appropriateness of applying the consumer-based model to health care and noting “few people shop for [medical care] like consumers, if only because of insurance”).
complicating factors\footnote{See, e.g., JAUNAR, supra note 7, at 107 (noting that “health information is imperfect,” patients are either “ill or under duress,” and that “even when good information is available, patients too often are passive consumers”); Hall & Schneider, supra note 20 (highlighting the problems with the patient-as-consumer view).} to provide satisfactory consumer-based answers. And consumer-based solutions fall particularly flat when applied to Medicare beneficiaries.\footnote{The example in the Medicare context is even starker because the Medicare beneficiary may not be paying monthly premiums—which would be different from an example of a privately insured individual. See Medicare 2016 Costs at a Glance, MEDICARE.GOV, http://www.medicare.gov/your-medicare-costs/costs-at-a-glance/costs-at-glance.html [http://perma.cc/PRC9-SPXJ] (last visited Mar. 6, 2016) (“Most people don’t pay a monthly premium for Part A (sometimes called ‘premium-free Part A’).”). But see Medicare Acute Care Episode (ACE) Demonstration, CMS.GOV (May 29, 2015), https://innovation.cms.gov/initiatives/ACE [http://perma.cc/R6UA-SXJ] (describing a demonstration that sought to “test the effect that transparent price and quality information has on beneficiary choice for select inpatient care”).} At a basic level, consumer-based answers “cannot sufficiently rationalize medical care expenditures because boundedly rational consumers cannot make the complex cost-benefit tradeoffs at the point of treatment that the theory demands,”\footnote{See Korobkin, supra note 18, at 528.} as Steven Brill shows.\footnote{See Brill, supra note 1.}

In a typical buyer-seller transaction, the seller owes the buyer no duty of loyalty and few general duties.\footnote{See, e.g., Kathleen McNamara Tomcho, Commercial Real Estate Buyer Beware: Sellers May Have the Right to Remain Silent, 70 S. CAL. L. REV. 1571, 1571 (1997) (“Caveat emptor, qui ignaro non debuit quod jus alienum emit—let a purchaser, who ought not be ignorant of the amount and nature of the interest which he is about to buy, exercise proper caution.” Caveat emptor, ‘let the buyer beware,’ puts a purchaser on notice to ‘examine, judge, and test for himself.’ The doctrine places the risk of hidden defects solely on the buyer when parties bargain at arm’s length.”).} It is not remarkable to state that, regarding matters of money, buyers and sellers have opposite goals. The analogy breaks down when applied to American health care. In fact, many of the patient-protective doctrines that have arisen and expanded over the last forty years—such as informed consent, patient autonomy and the right to refuse, and medical malpractice enforcement—would be foreign to a typical buyer-seller transaction. For example, few sellers outside of health care are required to disclose information that could encourage the buyer to decide against a purchase.\footnote{Indeed, other relationships could be analogous to the doctor-patient-payer relationship. Academics have compared the provider-patient enterprise to the mechanic-car owner relationship. See, e.g., Kathleen M. Sullivan, The Intersection of Free Speech and the Legal Profession: Constraints on Lawyers’ First Amendment Rights, 67 FORDHAM L. REV. 569, 580 (1998) (noting that “information asymmetry creates moral hazards (such as the incentive to lie about the gravity of a problem) for auto mechanics”). This relationship has been cited by scholars due to the presence of information asymmetry, which also undeniably exists in the health care context. See Abigail R. Moncrief, The Individual Mandate as Healthcare Regulation: What the Obama Administration Should Have Said in NFIB v. Sebelius, 39 AM. J.L. & MED. 539, 556 (2013). The “mechanic” relationship is one between a payer-consumer and provider wherein the provider has a monopoly on the expertise available. The consumer trusts the mechanic, just as the patient trusts the provider. Further, the mechanic has information that the consumer cannot know—or is too expensive for the consumer to know—about the status of the consumer’s vehicle. With the}
Patients are at a substantial information deficit when visiting the hospital or doctor. Unlike a typical buyer, the patient cannot access information available to the provider;95 indeed, “[p]atients rely so much on their doctors that their purchasing choices are severely constricted,” which further strains the consumer analogy.96 Not only is the provider an expert and the patient not one, but the relevant information is also difficult for the patient to attain, understand, and use.97 Patients are operating in a transaction in which they are nearly completely unprotected, which gives providers more power. Hall and Schneider note that the “[d]octors’ ‘monopoly’ power is intensified by patients’ almost irredeemable ignorance about almost all of almost every transaction.”98 This reality of the clinical relationship seems unlikely to change because patients are not typical consumers.

In addition to these bedrock concerns, other characteristics—including Medicare’s historical shortcomings, the uniqueness of health care as a good, and proxy and agency problems between patients and payers—complicate the consumer-based paradigm that animates many of the recent policy changes in American health care.

A. Medicare’s Structural Shortcomings

The consequences of Medicare’s financing structure illustrate the poor fit between consumer-based tools and health care. In particular, this structure affects Medicare’s four main constituents: patients, CMS, participating providers, and taxpayers. Understanding how these parties receive, regulate, administer, and pay for care within Medicare spotlights the deficiencies inherent in the consumer-based model of American health care.

Most significantly, insured patients—particularly Medicare beneficiaries—are generally free from typical economic pressures that affect buyers in other consumer contexts. Medicare beneficiaries enjoy generous coverage for procedures that are “reasonable and necessary.”99 And most Medicare beneficiaries pay a fraction of the overall cost of their health care.100

knowledge deficit, it may be easy for the mechanic to convince the consumer to purchase additional services to ensure the optimum performance of his vehicle.

Nevertheless, the mechanic may also be recommending a higher-priced upgrade because he stands to gain financially when and if the consumer heeds his recommendation. This concern is also present in the provider-patient relationship. Although the mechanic-car owner relationship may feature less information asymmetry than the provider-payer relationship does—the car owner may be able to utilize other sources to “check” the truthfulness or wisdom of the mechanic’s recommendations, unlike in health care—it still bears similarities in major characteristics. See Moncrief, supra.

95. See Moncrief, supra note 94.
96. See Hall & Schneider, supra note 20, at 652.
97. Id. at 645.
98. Id. at 653.
99. See 42 U.S.C. § 1395y(a) (2012) (the “reasonable and necessary” requirement); Health Insurance Claim Form, supra note 83 (certification language); see also Medicare Billing: 837P and Form CMS-1500, supra note 83 (“Medicare payment requires that an item or service ... [i]s
Thus, from a financial perspective, Medicare beneficiaries often have no incentive to avoid expensive or unnecessary surgeries—unlike patients who must pay for costs incurred.\(^{101}\) Stories like Brill’s are indicative of the major differences between health care and every other consumer good; consumer protections in other industries do not translate to health care.\(^{102}\) The absence of these pressures in the health care enterprise is undoubtedly liberating for the patient and the provider, but leaves a regulatory gap where providers’ self-interest can encroach.\(^{103}\)

Patients also may lack the capacity to ask the right questions. Even when a patient will be financially responsible for a hefty portion of the final hospital bill, she is unlikely to question whether she has been adequately informed of, for example, treatment alternatives, the necessity of an additional scan, or the price of aspirin that she needs in the moment she is experiencing a health care emergency. She, like Brill, is thinking about the pain or experiencing the fear and uncertainty that often accompany a malady. In that moment, the Medicare beneficiary is a patient, not a health care economist—or even a taxpayer who funds Medicare. This creates an environment where the potential for overtreatment—via a physician ordering tests that border on clinically unnecessary or undertaking surgeries that may or may not be clinically defensible\(^{104}\)—is pronounced.

\(^{100}\) See Brill, supra note 5 (comparing the cost breakdown for health care services for Medicare beneficiaries to those for either uninsured or privately-insured individuals).

\(^{101}\) See Korobkin, supra note 18, at 538 (“[P]atients are more conservative about seeking medical care when they are forced to spend their own dollars on that care.”).

\(^{102}\) For example, advertisements for the “new” CVS Health remind American consumers that “health is everything.” See Our New Name, CVSHEALTH, http://cvshealth.com/newsroom (last visited Jan. 29, 2015).

\(^{103}\) JAUHAR, supra note 7, at 107; Korobkin, supra note 18, at 540 (“Evidence strongly suggests that many patients would prefer for their physicians to make treatment decisions for them.”).

\(^{104}\) Prominent examples of overtreatment include administering various scans for pain—including EEGs, CTs, and MRIs—without any other risks of a more serious problem, as well as stent placement. See Gawande, supra note 8; Jordan Rau, Overused Medical Services Cost Medicare Billions of Dollars, NPR (May 12, 2014), http://www.npr.org/sections/health-shots/2014/05/12/311897685/overused-medical-services-cost-medicare-billions-of-dollars (noting the prevalence of “low-value” services in Medicare and concluding that 21.9 million low-value treatments were administered in 2009).

Other examples include prescribing expensive brand-name drugs and administering procedures on an inpatient basis when they could instead be administered on an outpatient basis. See Isaac D. Buck, Caring Too Much: Misapplying the False Claims Act to Target Overtreatment, 74 OHIO ST. L.J. 463 (2013) (highlighting the kyphoplasty initiative as an example of an enforcement initiative focused on the decision to perform surgeries on an inpatient basis).
Outside the Medicare program, additional deductibles, copays, and other forms of cost-sharing have made insured patients more sensitive to costs, but these reforms have been largely limited to private insurance plans. The lack of cost pressure on Medicare beneficiaries reveals both a valuable strength (Medicare patients pay less) and a structural vulnerability (Medicare providers game the system). Unsurprisingly, this vulnerability can create damaging conflicts of interest for Medicare providers. Legal efforts on the margins seeking to bolster consumer-based tools do not adequately address this risk.

In addition, CMS, the entity that oversees Medicare, has been hesitant to impose any cost-based limits on the types of care reimbursable under Medicare. And now, the program rests on shaky financial footing with a booming enrollment. As its finances became more precarious, CMS continued to protect nearly unlimited provider autonomy and failed to install public price controls that would have impacted clinical decision making over the last few decades. Clearly, the consumer-based model cannot control CMS’s reimbursement scheme.

To be fair, as is the case for private insurance carriers, Medicare faces a massive “information problem” in its attempt to fairly and accurately limit coverage to the most effective clinical treatments. Not only is it a challenge to make coverage determinations for procedures ex ante, but “measures of marginal effectiveness of competing interventions are dynamic”: once one treatment is deemed the most effective, another is ready to take its place.

Finally, the National Coverage Determination (NCD) process for the Medicare program is fraught with challenges—including a built-in bias for

105. The reforms brought about by the ACA directly address the cost-sharing scheme for private insurance plans. See KAISER FAMILY FOUND., PATIENT COST-SHARING UNDER THE AFFORDABLE CARE ACT (2012), https://kaiserfamilyfoundation.files.wordpress.com/2013/01/8303.pdf [http://perma.cc/8PX3-3MUL].

106. These tools include informed consent, patient autonomy and the right to refuse treatment, as well as civil litigation for malpractice. See Buck, supra note 88. However, informed consent remains a rather weak tool. See JAUNARI, supra note 7, at 107 (“For example, studies have shown that patients take little interest in the informed consent process.”). But see Korobkin, supra note 18, at 532–38 (documenting the complexities involved in medical decision making, including emotion, unclear information, the novelty of decisions, and the sheer complexity of a decision about a patient’s treatment plan).

107. See Fox, supra note 15, at 18.


109. See Fox, supra note 15.

110. See Korobkin, supra note 18, at 550 (“[T]here is very little solid information about even the basic effectiveness of most medical interventions—according to some estimates, there is scientific evidence for the efficacy of less than half the treatments doctors recommend.”).

111. Id.

112. Id. at 551.
approving new coverage determinations, the complete avoidance of considering cost during the determination process, and a lack of clear and adequately publicized rules governing the procedure—(and has led a prominent scholar to call the NCD process “political” and not scientifically accurate."

Attempts to reform certain aspects of Medicare have had limited success. ACA payment reforms, a reformed “doc fix” regime, and new payment models that reimburse based on cost and quality of care are just now being implemented, so it is unclear whether these models will help cut the unnecessary use of health care resources. Through Medicare Advantage plans, CMS is also relying on third parties, such as recovery audit contractors (RACs) and health maintenance organizations (HMOs), to try and limit cost increases, to mixed results.

Finally, where the ACA could have infused common-sense cost-effectiveness metrics into coverage decisions, it avoided that path. The ACA created the Patient-Centered Outcomes Research Institute (PCORI) to “improve the quality and relevance of evidence available to help patients, caregivers, clinicians, employers, insurers, and policy makers make informed health decisions,” but prohibited use of any of PCORI’s findings “as mandates for practice guidelines, coverage recommendations, payment or policy recommendations.” PCORI, as a result, occupies a precarious and

113. See Buck, supra note 11, at 1280–81.


115. See Robert Pear, Senate Approves a Bill on Changes to Medicare, N.Y. TIMES (Apr. 14, 2015), http://www.nytimes.com/2015/04/15/us/politics/senate-approves-a-bill-on-changes-to-medicare.html [http://perma.cc/TQ2X-8G8W] (describing the new reimbursement system as “payment based on the quality and value of care, rather than just the volume of services”). Federal officials have referred to the new framework as “not . . . a permanent solution” and have warned that the new system reduces payment for physicians in the Medicare program. Id.


117. See JAUHAR, supra note 7, at 97 (highlighting that even in more modern payment structures, incentives for excessive treatment still exist).

118. See discussion and accompanying notes, infra Part IV.

119. See About Us, PATIENT-CENTERED OUTCOMES RES. INST. (Oct. 6, 2014), http://www.pcori.org/about-us [http://perma.cc/8NRP-9E7Z] (stating that its “mandate is to improve the quality and relevance of evidence available to help patients, caregivers, clinicians, employers, insurers, and policy makers make informed health decisions”).

unpopular position in American health care politics—angering both conservatives and liberals.\(^\text{121}\)

Given the current reimbursement rules, providers have gamed the system where they can.\(^\text{122}\) With more time constraints,\(^\text{123}\) lower reimbursement rates,\(^\text{124}\) and a growing number of specialists and referrals,\(^\text{125}\) providers administer unnecessary services that directly result in higher costs.\(^\text{126}\) Under traditional reimbursement models, financial incentives are also powerful drivers of overtreatment. If a provider wants to make more money, he can perform more scans, stents, or tests—increasing the amount of “no-value care” he administers.\(^\text{127}\)

Other obvious incentives in the health care system seem designed to cause overtreatment and underutilization. For instance, through its reimbursement mechanism, Medicare financially incentivizes doctors to prescribe expensive medications like Lucentis.\(^\text{128}\) The policy also encourages providers to treat more patients and forces them to reduce the amount of time they spend with each patient, ultimately leading to more (often unnecessary) testing and scanning of those patients.\(^\text{129}\) Providers try to replace face-to-face time with an extra scan, but “[t]here is no more wasteful entity in medicine than a rushed (or incompetent) doctor.”\(^\text{130}\) The consequences—excessive and expensive scans and medications—are predictable. But CMS has not done enough, or done it quickly enough, to fix this delivery system.

In addition, the hospital or health group often controls the price of health care, with few limits.\(^\text{131}\) Where a seller powerfully controls the market,\(^\text{132}\) he can charge the buyer as much as he wants—especially when the buyer is in

\(121\) See id.
\(122\) See JAUHAR, supra note 7, at 97 (“Overtesting and overconsultation have become facts of the medical profession. The culture today is to grab patients and generate volume.”).
\(123\) Id. at 225–26 (noting that slashed reimbursement rates increase pressure to see more patients, and that “[a]part from the perverse incentives of our fee-for-service system, a major driver of overconsultation is the uncertainty engendered by the hurried pace of contemporary medicine”).
\(124\) Id. at 96.
\(125\) Id. at 97.
\(126\) See, e.g., id. at 94 (“In our health care system, if you have a slew of physicians and a willing patient, almost any sort of terrible excess can occur.”).
\(127\) See Gawande, supra note 8.
\(128\) See discussion and accompanying notes, supra Part I.
\(129\) See JAUHAR, supra note 7, at 54 (“Technology like MRI scans and nuclear imaging rules the day, permitting diagnosis at a distance. Many doctors don’t even carry a stethoscope anymore.”).
\(130\) Id. at 226.
\(131\) See Brown, supra note 33, at 14 (“Hospital prices are characterized by mind-boggling complexity, opacity, unfair and inefficient price discrimination, and wide variations. . . . Not only do different hospitals charge vastly different prices for the same service, but the same hospital charges different prices to different payers.”).
\(132\) See Brill, supra note 5 (noting the weaknesses of the American patient, or consumer of health services, at the time of most need).
pain or under stress, as is the case in the medical industry.⁷³ Alone, no number of consumer-based tools will rationalize hospital and physician prices. 

Lastly, although taxpayers fund Medicare,⁷⁴ few legal solutions have proposed increasing the taxpayer’s involvement—perhaps because CMS is viewed as a proxy for the millions of Medicare payers. Those funding the program have an undeniable interest in limiting waste within the Medicare program⁷⁵ to safeguard its financial viability, but they have limited tools to do so. CMS’s failure to adequately incorporate cost-effectiveness into coverage decisions and reimbursement policies demands a new solution. 

B. The Uniqueness of Health Care Goods 

In addition to the complications from pain,⁷⁶ lack of price pressure, and information asymmetry, Professor Mark Hall has highlighted that medical patients are seeking something different than buyers in other contexts.⁷⁷ Indeed, “[s]omeone who is ill and seeking help—unlike someone who is purchasing a pair of socks or a pound of sausages—is often vulnerable, certainly worried, sometimes uncomfortable, and frequently frightened.”⁷⁸ In this way, health care is unlike any other consumer good. 

It is also more personal than other consumer goods. A health care purchase is more individual than a purchase in just about any other industry; each patient’s treatment is unique. If a patient reads that too many cardiac stents are being placed in patients in her locale, but her provider informs her that she really needs one because her cardiac disease is severe, the patient will likely agree. Sure, providers may be overly aggressive in placing stents in others, but she really needs one. These tensions also make it a challenge to craft utilization limits that are dependent on patients. 

Health care needs persist even when one’s health improves or changes. Whereas buying a new refrigerator satiates the consumer’s need, receiving health care does not necessarily satiate the patient. For example, an annual physical is considered a necessity, people may gain muscle or lose weight, and preventive treatment is clearly acceptable.⁷⁹ If a consumer is interested in

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133. See Hall & Schneider, supra note 20, at 652 (characterizing the doctors’ power over patients as a “monopoly”).
135. See Mary Ann Baily, Futility, Autonomy, and Cost in End-of-Life Care, 39 J.L. MED. & ETHICS 172, 175 (2011) (arguing that “the people who pay the premiums and taxes that support private and public insurance” should have their autonomy considered).
136. See Hall & Schneider, supra note 20, at 650–51 (noting that illness, inter alia, “disables,” “pains,” “exhausts,” “erodes control,” “enforces dependence,” “disorients,” “baffles,” “terrifies,” and “isolates”).
137. See, e.g., Hall, supra note 21 (documenting the importance of trust in the clinical relationship).
138. Hall & Schneider, supra note 20, at 651.
purchasing a product that he can always use more of, does not pay (much) for, and that his personal expert provider recommends, nothing dissuades that consumer from agreeing to that purchase.

The individualism inherent to health care also limits regulators. Individualized health care complicates the regulatory scheme by making it more difficult to initially discern that financial harm has occurred and to convince the patient that they have received overtreatment. For a regulatory regime to have popular backing to adequately provide redress, the harmed party has to actually know that she was harmed. Fraud and abuse laws help address fraudulent billing schemes, but the financial harm of excess—the “grey” harm to Medicare caused by American overtreatment—is diffuse. It is not borne by one taxpayer, but spread among all of them. Like an oil spill leaking into a remote body of water, Medicare’s chronic overtreatment problem directly devastates very few individuals. Taxpayers may be pained by the problem when they see it, but they may not feel it. And when the Medicare program is overcharged, taxpayers may get squeezed, but patients (typically) do not die. In short, few victims of the enterprise are clamoring for immediate recompense.

C. Agency and Proxy Problems

A final major challenge associated with the attempt to regulate Medicare utilization is the agency problem. The one party interested in limiting costs and utilization—the taxpayer—has no true agent in the hospital room. In some instances, the provider’s interests may be in direct conflict with the taxpayer’s, while the patient cannot be a good agent for the taxpayer. In the clinical setting, the patient’s needs easily subvert the taxpayer’s desires. Patients like Steven Brill happily craft a narrative that the provider is thorough, caring, heroic, altruistic, and aggressive, as long as the provider is healing him.

Without an individual with a vested interest in limiting overtreatment present in each hospital room, the payer’s power is blunted, if not vanquished.


141. See Brill, supra note 1, at 38.

142. See id.
In the clinical setting, the taxpayer has no direct interaction with the provider; the taxpayer interacts with the provider only through Medicare reimbursement policies and NCDs. CMS’s influence on the provider seems obvious: through extensive payment regulations and requirements, Medicare appears to appropriately constrict the provider’s treatment options to cost-effective options. But in many clinical scenarios, the provider retains unlimited discretion to choose among options that range in cost-effectiveness.

Most important, the provider retains nearly unlimited control over how particular patients are treated. For instance, Medicare’s reimbursement regulations are not granular enough to only pay for lower back x-rays for patients who truly need them. Without an agent, Medicare cannot differentiate these doctors from providers who perform unnecessary x-rays because they are being aggressive, safe, or crooked, or lack time to converse with the patient.

If little binds the patient-provider enterprise and the payer, the payer possesses little influence over the moment when the provider and patient determine a treatment plan. The combination of the payer’s weakness and CMS’s inaction with the problems inherent in relying on patients to limit overtreatment makes clear that without a limiting force in the clinical decision-making process, overtreatment proliferates.

Indeed, few would argue that it is bad when patients feel empowered, unencumbered by government rationing, and able to elect what they feel is truly best for them. But concluding that the beneficiary and provider should enjoy a decision-making capacity that binds the payer to fund the chosen service does not mean that the provider should enjoy unlimited discretion. Perhaps the solution is not imposing new reimbursement regulations, but instead, a regime shift that recognizes a flexible new legal relationship between providers and payers.

D. Duct Tape: Ethics and Encouragement

Outside of fraud and abuse enforcement, which are difficult to appropriately apply to overtreatment, Medicare policy has largely punted on the utilization question, leaving cost-effectiveness to physician ethics codes. Aside from these ethics codes and Medicare reimbursement guidelines that feature the vague requirement that all administered care be “reasonable and

143. In fact, Medicare’s most limiting regulation—that all care must be reasonable and necessary—features standards that are vague and broad. See 42 U.S.C. § 1395y(a) (2012).
144. See JAUHAR, supra note 7, at 97.
145. See Baily, supra note 135, at 175 (“Although reasonable limits on care are in the long run interest of patients, in the short run, patients do not like to be told no. Moreover, the general public does not really understand the need for limits. It does not understand that access to beneficial care is already limited in a myriad of hidden ways that are anything but fair and reasonable. So, the general public fears anything that can be given the label of ‘rationing.’”).
146. See, e.g., Buck, supra note 88.
necessary.”  The provider’s discretion over clinical decisions has been largely unregulated and untouchable. More recently, specialty groups have tried to inform providers of the most routinely overused procedures and tests, but these modern moves have failed to overcome a physician culture that has been “notoriously resistant to cost-effectiveness principles or, more generally, to serving the collective needs of the community as a whole at the expense of identifiable individuals.” There are three main reasons for this.

First, this quasi-regulatory environment, which relies on ethics codes to keep doctors from practicing profit-padding overtreatment, puts doctors in the middle of an inexorable conflict. Historically, Medicare’s reimbursement policy pushed them to administer more health care to make money, but their aspirational ethical tenets have ignored these realities. Physician ethics codes speak from a time when medicine was simpler, patient-centered, and focused on avoiding physical harm. And without legal enforcement of these ethical tenets, the profit motive may weaken the power of the physicians’ codes of ethics.

Second, the codes themselves lack explicit rules about overtreatment. Physicians can easily argue that, when ordering the potentially unnecessary lower-back screen, they were placing their patient first by simply being “aggressive.” Nothing in that situation is illegal or even unethical, but administering unnecessary health care to patients is harmful to both patients and taxpayers. Physicians’ clinical discretion and expertise provide a problematic cover for this harm.

Finally, the ethics codes do not even mention the payer. Cost has become an unmentionable in American hospitals and clinics, as if the health care enterprise is somehow above its moneymaking goals. This phenomenon has filtered down to the provider. In some ways, the physician operates in a vacuum, concerned only about treatment and the patient. For instance, the payer is not mentioned in the American Medical Association Code of Ethics

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147. See 42 U.S.C. § 1395y(a).
148. See Mantel, supra note 30, at 127 (“Medicare’s design affords physicians unfettered discretion over the medical care provided to their patients. This discretion allows physicians to exert tremendous influence over how much Medicare spends on patient care.”).
150. Korobkin, supra note 18, at 544–45.
152. See, e.g., Buck, supra note 11, at 1292–97 (documenting a recent enforcement action against practitioners who adopted aggressive clinical strategies).
153. See Brill, supra note 1 (demonstrating the rude awakening for many patients when, upon recovery and discharge, they realize that everything in a hospital comes with a price tag); see also Hall, supra note 21 (claiming that if medicine discussed money, it would cheapen the profession).
The closest the Code gets to explicitly mentioning cost is Opinion 6.05:

A physician should not charge or collect an illegal or excessive fee. For example, an illegal fee occurs when a physician accepts an assignment as full payment for services rendered to a Medicare patient and then bills the patient for an additional amount. A fee is excessive when after a review of the facts a person knowledgeable as to current charges made by physicians would be left with a definite and firm conviction that the fee is in excess of a reasonable fee. Nothing in the Code addresses when a provider should discuss cost with a patient, or when—if at all—cost should factor into clinical decision making.

Regarding utilization, the codes remind physicians that they “should not provide, prescribe, or seek compensation for medical services that they know are unnecessary.” But this provision bans health care fraud, rather than encouraging providers to be conscientious stewards of health care resources. Clearly, an industry unconcerned with cost may have trouble adopting a successful consumer-based model.

III.

THE LAW OF THE FIDUCIARY

Application of the fiduciary paradigm to the provider-payer relationship in Medicare shifts the analysis—and recognizes a duty of loyalty between Medicare’s providers and its payers—but does not provide specific regulatory guidance or rules to govern that legal relationship. Indeed, “fiduciary law does not consist of an integrated body of concrete rules or precise doctrine that applies uniformly to all forms of fiduciary relationships.” Nevertheless, throughout disparate enterprises, central tenets govern the application of the fiduciary relationship. A summary of these characteristics follows.

A. General Applicability

A number of general characteristics typically define recognized fiduciary relationships. According to Professor Tamar Frankel, these are: (1) fiduciary relationships are usually service relationships; (2) fiduciaries themselves are entrusted with power; (3) the fiduciary’s goal is to serve the entruster, or principal; (4) the relationship features excessive monitoring costs; (5) the

154. See American Medical Association Code of Medical Ethics, supra note 151.
157. Hall, supra note 21, at 490.
relationship features services for which the entrustor has little comparative expertise; and (6) other external controls are too weak.

Fiduciary law is vital to relationships that require something extra from the law; it can “replace social controls that have weakened.” The theory is appropriate for an increasingly specialized workforce where “pooling,” or the “transfer of resources by many persons to a small number of experts,” occurs. Pooling is efficient for society, but nakedly exposes the consumer-entrustor’s great weakness.

Put another way, a fiduciary relationship is appropriate when the fiduciary is more expert than the entrusting party, when the entrusting party “wish[es] to be relieved from performing the activities personally,” or when the entrustor “may not want to give up the time or make the commitment that the activity requires.” Not all relationships that feature one or more fiduciary characteristics are recognized as a fiduciary relationship; indeed, the existence of one or two fiduciary characteristics does not transform a fundamentally nonfiduciary relationship into a fiduciary one. Nevertheless, the distinctions are quite blurry.

According to Frankel, substitution and enabling are the two central features of the fiduciary relationship. The fiduciary both serves as a substitute for the entrustor and “obtains power from the entrustor or from a third party for the sole purpose of enabling the fiduciary to act effectively.”

Substitution and enabling give rise to the “central problem” of the fiduciary relationship—the potential for the abuse of power by the fiduciary. The entrustor is at risk of injury should the fiduciary misuse his power; however, should the entrustor either reduce the power granted to the fiduciary or increase monitoring or control of the fiduciary, or both, the entrustor “reduce[s] the benefit expected from the relation.” In other words, the delegation of power and substitution bestowed on the fiduciary are what make

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158. The entrusting party is the principal, or the party for whom the fiduciary acts and to whom he owes a duty.
161. *Id.* at 804.
162. *Id.*
163. *Id.* at 808.
164. *Id.*
165. *Id.* at 809.
166. *Id.* at 808.
167. *Id.* at 809.
168. *Id.*
169. *Id.*
the fiduciary relationship so beneficial for the entrustor, and the entrustor loses that benefit if he has to monitor the fiduciary.

Others refer to this as the “central agency problem.” Professor Robert Sitkoff has argued that the “agency problem arises whenever one person, the principal, engages another person, the agent, to undertake imperfectly observable discretionary actions that affect the welfare of the principal.” Further, according to Sitkoff:

Agency problems are pervasive because no one has the skills necessary to do everything for himself and because every undertaking has an opportunity cost. By delegating a task to an agent, the principal benefits from specialist service and is freed to undertake some other activity. But these benefits come at the cost of being made vulnerable to abuse if the agent is given discretion the exercise of which cannot easily be observed or verified.

As another scholar put it:

If contracting parties could provide rules to govern every potential conflict of interest between them, then there would be no need for fiduciary law. But often they can’t. Courts enforce fiduciary duties where one party hires the expertise of another, on the “obvious condition” that she not be “at the mercy of an agent” she cannot monitor.

Because the fiduciary relationship provides protection from the agency problem, scholars have applied this protection to an ever-expanding pool of relationships.

The agency problem also applies to the Medicare payer-provider relationship. Medicare and its taxpayer funders have delegated to participating providers the task of administering health care to its beneficiaries. But CMS, the taxpayer’s proxy, cannot be in every hospital room to ensure that every stent placement is medically necessary. Regulating this relationship requires stronger legal tools.

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170. Robert H. Sitkoff, An Economic Theory of Fiduciary Law, in PHILOSOPHICAL FOUNDATIONS OF FIDUCIARY LAW 198 (Andrew S. Gold & Paul B. Miller eds., 2014); see also D. Theodore Rave, Politicians as Fiduciaries, 126 HARV. L. REV. 671, 677 (2013) (proposing that “political representatives should also be treated as fiduciaries, subject to a duty of loyalty” because of agency problem present in governing).

171. Sitkoff, supra note 170, at 199.


B. The Patient-Provider Fiduciary Relationship

The recognized fiduciary relationship in American health care—according to both the academy and the courts—is the relationship between the provider and the patient, although this is up for debate. Indeed, the legal academy has focused extensively on the relationship between the patient and provider, with the debate centering on whether or not the fiduciary metaphor is a positive and necessary development for patients, or a duplicative, harmful, trust-reducing one. Professor Maxwell Mehlman, who supports the application of the metaphor to the patient-provider relationship, argued that:

Fiduciary law protects patients and similar parties by providing them with powerful procedural advantages compared with common law plaintiffs. In effect, fiduciary law offsets a weaker interpersonal position in the fiduciary relationship with a stronger legal position in the event of a breach by the fiduciary. He further argued that although the fiduciary metaphor is under attack, the relationship must remain entrenched in the patient-provider relationship, particularly because “physician loyalty is essential for patient well-being.”

Professor Anna Laakman extended the fiduciary argument to physician innovation. She proposed a fiduciary framework that requires physicians, when innovating, to act in the best interests of their patients in a deliberative and loyal way, but that protects the sanctity of the physician’s substantive treatment decision in a given clinical setting without exposing the physician to liability.

Although courts are not unanimous, many have held that the medical provider is a fiduciary to patients, and the patient-provider relationship

174. See Hall & Schneider, supra note 20, at 678–79 (“Doctors have undoubted fiduciary duties to their patients.”).
175. See Maxwell J. Mehlman, Why Physicians Are Fiduciaries for Their Patients, 12 IND. HEALTH L. REV. 1, 10–12 (2015) (citations omitted) (“What does come as a surprise are the sources that cast doubt on or reject outright the fiduciary nature of the patient-physician relationship. These include judicial opinions as well as Restatements, legal treatises, scholarly articles and monographs. Even the Supreme Court has muddied the waters.”).
177. Mehlman, supra note 176, at 1148; see also Hall & Schneider, supra note 20, at 668 (“The law responds to patients’ exceptional vulnerability by altering several assumptions about commercial relationships. For example, the law spurns caveat emptor and the presumption that parties contract at arm’s length and instead makes the doctor a fiduciary.”); Mehlman, supra note 175, at 17 (“The reasons for denonominating the patient-physician relationship as ‘confidential’ or one of ‘trust and confidence’ rather than fiduciary are unclear.”).
178. Mehlman, supra note 176, at 1172.
179. See Laakman, supra note 22.
180. See, e.g., Moore v. Regents of the Univ. of Cal., 793 P.2d 479, 483 (Cal. 1990) (recognizing, in an informed consent context, that the physician has a “fiduciary duty to disclose all information material to the patient’s decision”); Estate of McRae, 522 So. 2d 731, 737 (Miss. 1988)
seems to meet most, if not all, of Frankel’s factors for a fiduciary relationship.\textsuperscript{181} Despite this, the actual application of fiduciary guidance to the physician-patient relationship has been more complicated.\textsuperscript{182} Courts have treated physicians as fiduciaries in scenarios involving “disclosure and informed consent, patient confidences, and not withholding or fraudulently concealing information patients or related third parties are entitled to receive.”\textsuperscript{183} Further, “courts also have extended fiduciary law to protect the vulnerable status of patients where physicians may exercise discretionary power over them,”\textsuperscript{184} and have also imposed fiduciary duties on institutional providers.\textsuperscript{185} If not universal, recognition of the relationship is substantial.

In addition, Professors Hall and Schneider have observed that, like regulation of health care delivery, the financial aspects of care would be served well by a fiduciary analysis.\textsuperscript{186} They focus on overcharging the patient as the evil in need of a remedy.

Doctors are fiduciaries because patients are medically at their mercy:

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(\textsuperscript{181} The Frankel factors apply to Medicare as follows. First, providers are administering a service by providing health care to elderly patients. Second, participating doctors are entrusted with power to administer medically necessary and reasonable health care services to those Medicare beneficiaries. They are expected to use their expertise and abilities to administer care. Third, providers have an ethical and legal duty to treat people who become patients. Fourth, the patient-provider relationship features excessive monitoring costs. Providers determine what is medically necessary, what prescriptions are appropriate, and whether or not to perform surgeries or scans. It is very difficult for patients to understand whether a procedure was appropriate and successful, and the costs for patients to monitor providers are prohibitive. Fifth, patients have little comparative expertise. Sixth, patients are often at the provider’s mercy. The patient-provider relationship thus seems to squarely fit within the fiduciary metaphor.)

\textsuperscript{182} \textit{See} Mary Anne Bobinski, \textit{Autonomy and Privacy: Protecting Patients from Their Physicians}, 55 U. PITT. L. REV. 291, 348–49 (1994) (stating that “[t]here has been little judicial analysis of the appropriateness of applying fiduciary-based disclosure obligations to the physician-patient relationship,” but noting that “[s]everal treatises on fiduciary law name the physician-patient relationship as a fiduciary one and the courts have tended to concur”) (citations omitted); Thomas L. Hafemeister & Selina Spinos, \textit{Lean on Me: A Physician’s Fiduciary Duty to Disclose an Emergent Medical Risk to the Patient}, 86 WASH. U. L. REV. 1167, 1167 (2009) (“Courts and commentators have widely acknowledged that [the fiduciary] duty exists because of the nature of the special relationship between a physician and patient. Application of this duty has been sparse, however, in part because its jurisprudential foundation has received virtually no attention.”).


\textsuperscript{184} \textit{Id. at} 728.

\textsuperscript{185} \textit{Id. at} 729.

\textsuperscript{186} \textit{See} Hall & Schneider, \textit{supra} note 20, at 680–81.
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Unnegotiated, open-ended contracts make patients as vulnerable financially as they are medically. Charging uninsured patients several times more than patients protected by private insurers or government regulators flagrantly exploits patients’ financial, physical, and psychological vulnerability. Fiduciary law is equipped with principles which cry out for application in such circumstances.\textsuperscript{187} But their work recognizes the potential for fiduciary application to the patient-provider relationship to protect the patient financially. The instant analysis builds on that argument and suggests that a fiduciary duty relationship should actually run from the provider to the ultimate payer—in this case, taxpayer-funded Medicare. In requiring the provider to owe duties of care and loyalty not just to the patient but also to the payer, this analysis assumes that Hall and Schneider’s application of the fiduciary analysis to the patient’s financial wellbeing is correct.\textsuperscript{188} This Article also argues that the fiduciary analysis applies in situations where the patient is not financially responsible for whatever amount the hospital seeks to charge, which is often the case for the Medicare beneficiary.

\textbf{IV. PHYSICIANS AS FIDUCIARY STEWARDS}

The central contribution of this proposal to recognize a payer-provider fiduciary relationship is to impose on providers a duty of loyalty to Medicare’s payers. In the fiduciary relationship, the agent must satisfy a primary duty of loyalty.\textsuperscript{189} An action for breach of fiduciary duty does not require proof that the provider breached a due care standard,\textsuperscript{190} but centers on whether the agent was self-interested. The duty of loyalty “proscribes misappropriation and regulates conflicts of interest by requiring the fiduciary to act in the ‘best’ or even ‘sole’ interests of the principal,”\textsuperscript{191} whereas the duty of care is an “objective”

\textsuperscript{187} Id. at 681.

\textsuperscript{188} Id. (presenting supervisory doctrines as tools courts can use to protect patients and address their vulnerability).

\textsuperscript{189} See Mehlman, supra note 177, at 27 (“Of course, a claim that a physician breached a fiduciary duty is not the same as a claim that the physician committed medical malpractice. The former deals with whether or not the physician acted loyally, while the latter deals with whether the physician acted with due care.”).

\textsuperscript{190} Thomas L. Hafemeister & Richard M. Gulbrandsen, Jr., The Fiduciary Obligation of Physicians to “Just Say No” if an “Informed” Patient Demands Services that Are Not Medically Indicated, 39 SETON HALL L. REV. 335, 379–80 (2009) (“An action for breach of fiduciary duty, however, does not require the patient to demonstrate that the physician failed to exercise due care. Instead, the plaintiff need only show that the physician’s conduct violated basic rules of conduct regarding how all physicians are expected to act, for which expert testimony may not be required.”).

\textsuperscript{191} Sitkoff, supra note 170, at 201. Indeed, where a fiduciary is in structural conflict with his beneficiary, he will not be held to account under fiduciary law unless he acts in accord with his own interests and to the detriment of his beneficiary. See Mehlman, supra note 175, at 21.
standard, one “establishing a ‘reasonableness’ or ‘prudence’ standard that is informed by industry norms and practices.”

In the provider-payer relationship, the loyalty duty would require the provider to be loyal to the best interests of taxpayers who fund Medicare. This is not a novel concept. Others have called for a stewardship duty for providers. Indeed:

Physicians and other individual and organizational providers of treatment are the stewards of these funds and have a duty to use them only for uses that are consistent with the understandings that underlie the formation of the pools. Not doing so violates the autonomy of those who have paid into them.

But this paradigm has not yet taken hold in the law; thus this proposal seeks to advance it. Moreover, current reform efforts are inadequate.

A. The Inadequate Toolset

Upon recognizing its unsustainable financial footing, Medicare has begun to adopt new cost-saving tools. Increasingly, the program is using accountable care organizations (ACOs), bundled payment regimes, Medicare managed care programs, and RACs, to tackle excess utilization and cost. Still, a regulatory gap remains.

The fiduciary duty solution would be yet another tool to strengthen Medicare cost-containment efforts. For example, a new fiduciary duty would supplement the “carrots” in the program’s modernizing reimbursement regime by reaching scenarios that are not captured by the new paradigm. Further, it remains unknown whether those recent policy changes will achieve the necessary cost savings.

In an effort to streamline and coordinate care, the ACA has incentivized health groups, physicians, hospitals, and other providers to form coordinated health delivery networks called ACOs, which share “financial and medical responsibility for providing coordinated care to patients in hopes of limiting unnecessary spending.” Regulators hope that ACOs will usher in a new era in health care delivery—one in which providers have a direct financial interest

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193. See Baily, supra note 135, at 175.
194. Id.
in providing more efficient care.\textsuperscript{198} Years after they were called “unicorns” because few patients had come into contact with ACOs, these new networks have begun to proliferate.\textsuperscript{199}

Even though CMS has stated that ACOs “continue to improve the quality of care for Medicare beneficiaries, while generating financial savings,”\textsuperscript{200} the verdict on whether ACOs are saving money is mixed.\textsuperscript{201} And while twenty ACOs are enrolled in the so-called Pioneer ACO program and more than 330 Medicare ACOs are enrolled in the Medicare Shared Savings Program (MSSP),\textsuperscript{202} long-term cost-savings forecasts remain unclear.\textsuperscript{203}

The ACO model has also been subject to criticism. Many of the entities able to take on the financial risk necessary to enroll in the ACO program are large entities, or the types of large entities that “are still being reimbursed under [a] traditional fee-for-service payment model,”\textsuperscript{204} which makes them much less likely to try to control costs.\textsuperscript{205} Others have criticized the accounting practices employed by CMS, which seem to paint a picture rosier than the reality.\textsuperscript{206} For instance, a proposed change to the way CMS calculates whether ACOs in the MSSP are saving the program money would result in increased findings of savings.\textsuperscript{207}

\begin{thebibliography}{99}
\bibitem{198} See Are Medicare ACOs Working?, supra note 196.
\bibitem{202} Medicare ACOs Provide Improved Care While Slowing Cost Growth in 2014, supra note 200.
\bibitem{203} See Are Medicare ACOs Working?, supra note 196.
\bibitem{204} Id.
\bibitem{205} Id. Robert Murray, the president of Global Health Payment, continues: For hospitals, which have high levels of fixed costs, the way to cover costs and earn profits is to generate more volume. Their incentives run directly counter to the goals of the ACO program, which are to reduce costs, to reduce unnecessary use of hospitals and high-priced professionals. The ACO model for these groups is akin to asking an overweight patient to eat his or her own flesh to become thinner. Id.
\bibitem{206} Id.
Notwithstanding the challenges, many remain cautiously optimistic regarding ACOs’ abilities to save money.

Reviews of ACO programs’ quality of care also offer mixed results. Some experts note that entities participating in Medicare’s ACO programs—which remain strictly voluntary—have reportedly improved Medicare’s care quality. But other analyses suggest that quality of care in the ACO program was “weak” in 2014. According to a recent analysis of care quality, the “top financial performers [in the program] did so poorly that none ranked in the top 90th percentile nationally.” These numbers have “raise[d] questions about the accuracy of quality measures in the [ACO] program.”

In addition to the unanswered quality and cost questions, there is a concern that ACOs—particularly for private payers and not necessarily Medicare—incentivize further consolidation in the health care marketplace. By pushing coordination, ACOs may harm competition and lead to higher total prices. Specifically, many in the industry are “joining forces and purchasing physician practices, leaving fewer independent hospitals and doctors. Greater market share gives these health systems more leverage in negotiations with insurers, which can drive up health costs and limit patient choice.” Suffice it to say that any conclusions about ACO effectiveness remain tentative.

In a second reform, CMS is seeking to change its Medicare reimbursement regime from a fee-for-service model to reimbursement on the basis of global, or bundled, payments. HHS Secretary Sylvia Burwell made headlines in January 2015 when she asserted that Medicare would seek to pay up to 50 percent through alternative reimbursement models (including bundled payments) by 2018. This is an ambitious plan, but by March 2016, 30 percent of Medicare’s reimbursements were made through alternative payment models.

Achieving those goals requires agreeing on the definition of “value,” ensuring an adequate amount of performance data and accounting metrics, and assisting physicians with considerable administrative costs incurred by moving away from assessing ACO benchmarks based on historical spending, and instead analyze trends in regional fee-for-service costs”.

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209. See *Are Medicare ACOs Working?*, supra note 196.


211. Id.

212. See *Gold*, supra note 197.

213. See *Better, Smarter, Healthier*, supra note 16.

increased data reporting. Bundled payments also face the classic threat that “[a]lthough the cost of each bundle may be reduced”—that is, each care episode for which Medicare will reimburse under a bundled payment method may become more efficient—“without any control over the volume of bundles provided, overall spending may not go down.” In theory, bundled payments incentivize providers to limit the costs per bundle, but do not limit the number of bundles of care that a provider administers.

In a third reform, Medicare has also adopted a traditional cost-saving tool used in the private health care insurance industry. Through Medicare Advantage, managed care has come to Medicare. As of 2015, more than 16 million people, or roughly 30 percent of all Medicare beneficiaries, were enrolled in Medicare Advantage plans (or Medicare Part C).

Medicare Advantage allows private insurers to provide coverage for Medicare beneficiaries. Medicare Advantage “must cover all of the services that Original Medicare covers except hospice care,” but may also cover additional benefits. Like HMOs before them, these plans import a number of cost-constraining techniques from the private insurance marketplace: referrals to see specialists, approved networks, higher coinsurance or copayment amounts for out-of-network services, and medical savings account options.

But Medicare managed care has faced many of the same criticisms as the private insurance experience. The HMOs that offer Medicare Advantage plans have come under increased scrutiny, with dozens fined in 2014. These enforcement actions have exposed a “very long pattern of misbehavior of

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216. Id. Under the Bundled Payments for Care Improvement Initiative, CMS has the authority to design and implement payment bundling models. Bundled Payments for Care Improvement Initiative, HEALTH AFF. (Nov. 23, 2015), http://healthaffairs.org/healthpolicybriefs/brief_pdfs/brief_policybrief_148.pdf [http://perma.cc/RSC7-GQ3A] (“CMS hopes that by paying for related care as part of a broad payment bundle, different providers that treat a patient during a single episode will have incentives to better coordinate care, avoid unnecessary services, and improve patient health.”).


220. Id.

221. See id.

222. See Herman, supra note 217 (noting that “insurance companies of all sizes are increasingly finding themselves in similar situations with the government,” and that “nearly three dozen health insurance companies have faced . . . fines . . . or, worse, temporary suspension from enrolling or marketing to new Medicare members”).
Medicare HMOs, including, in one case, allegations of systemic failures causing "inappropriate delays or denials in receiving covered benefits" that allegedly resulted in "inappropriate delays in access to medications or not receiving the appropriate appeal rights," Recent lawsuits—including as many as six alleging systematic overbilling by Medicare Advantage plans—have focused attention on the adequacy of government oversight of these plans.

In addition to these allegations, which mirror some of the criticisms of HMOs in the 1990s and early 2000s, Medicare HMO plans have not saved money. To some extent, this is because Medicare Advantage plans’ budgets are linked to Medicare’s spending. As a result, the amounts spent on Medicare Advantage plans rise with the cost of health care.

From a cost perspective, Medicare Advantage has been criticized as "fall[ing] short of replicating a competitive market outcome," which prevents it from being "fully cost-effective." Until passage of the ACA, Medicare Advantage plans were "receiving payments in excess of 114% of [fees for services rendered]," resulting in dramatic overpayments. Current cost results

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223. Id.
230. Id. at 240. Alleged fraud in the system has also presumably led to increased costs. See Schencker, supra note 226 (noting that “OIG estimated that . . . Medicare made $11.8 billion in improper payments—$9.3 billion in overpayments and $2.6 billion in underpayments—because of errors related to risk adjustment”).
of Medicare Advantage plans are “mixed,” and HMOs may be “slightly more efficient” than traditional fee-for-service delivery. Overall, however, Medicare Advantage has been “characterized by considerable inconsistency.”

Finally, Medicare’s RACs seek to investigate anomalies and waste within the Medicare program. RACs are charged with “identify[ing] and correct[ing] Medicare improper payments through the efficient detection and collection of overpayments made on claims of health care services provided to Medicare beneficiaries, and the identification of underpayments to providers.” RACs utilize “post-payment” review, which employ “data mining and other analytical techniques to identify potentially improper claims that lead them to focus on a small subset of submitted claims.” These entities “are required to employ . . . nurses, therapists, certified coders and a physician” on staff. RACs are a relatively new creation started through a demonstration project as part of the Medicare Modernization Act of 2003.

In that short lifespan, and not unlike other Medicare reforms, RACs have faced criticism. Their investigations are burdensome for providers and trade associations and congressional reports have criticized their fee arrangements and incentive structure. The RAC “incentive structure is based on recovering money that Medicare shouldn’t have paid, rather than reducing improper

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231. Greaney, supra note 229, at 243.
232. Id.
234. Id.
236. Mantel, supra note 30, at 130 n.43.
237. THE RECOVERY AUDIT PROGRAM AND MEDICARE, supra note 235.
claims.” Because RACs are paid on a contingent-fee basis, they are often incentivized to appeal large claims, so appeals are severely backlogged. Further, a recent report found that hospitals belonging to the American Hospital Association were highly successful in winning appeals—achieving reversals in more than 70 percent of appeals of inpatient claims denials. RACs typically keep around 10 percent of Medicare’s recouped overpayments as profit.

RACs have also recently endured withering criticism from Congress due to the contractors’ apparent ineffectiveness. Nonetheless, CMS wants to use RACs for Medicare Advantage plans—ironically to police and prevent improper payments in those plans as a result of inflated risk scores.

Just like the HMO solution imported from the 1990s, the RAC solution—another attempt to insert a third party with a profit motive into the enterprise—does not appear to provide a satisfactory answer, particularly because providers can claim that a government bureaucrat or nameless supervisor is driven not by ensuring quality clinical care and medical necessity, but by maximizing profit. The expert party is squeezed out, the regulatory body or third-party entity comes “between you and your doctor,” and, the narrative goes, patients and providers are the worse for it. This critique seems to follow any cost-containment solution that features a nonprovider third party.

248. Indeed, commentators have argued that preserving the freedom of the patient-physician relationship and allowing the provider and patient to build trust is a vital characteristic of the healing relationship. See Hall, supra note 21. Americans do not trust bureaucrats to handle resourced-based health care decisions. See Section-by-Section Review Reveals New Dangers in Democrats’ Government Takeover, SPEAKER.GOV (Aug. 16, 2009), http://www.speaker.gov/general/detailed-analysis-house-democrats-bill-will-lead-rationing-health-care [http://perma.cc/69BL-2PAR] (noting that Americans “oppose [the] scheme for a big-government takeover of health care that will raise costs, ration care, and put bureaucrats in charge of decisions that should be made by patients and doctors”). According to The Washington Post, former Alaska Governor Sarah Palin posted the following in response to the ACA:

The America I know and love is not one in which my parents or my baby with Down Syndrome will have to stand in front of Obama’s “death panel” so his bureaucrats can decide, based on a subjective judgment of their “level of productivity in society,” whether they are worthy of health care. Such a system is downright evil.
These Medicare cost-control tools—ACOs, bundled payments, Medicare Advantage, the deployment of RACs, and even the recent reimbursement changes proposed by CMS—may achieve cost savings, but the imposition of a fiduciary relationship would bolster these efforts. The fiduciary duties would reach those situations that ACO formation and bundled-payment efforts do not—scenarios like the Avastin and Lucentis example. Further, early results from the ACO program are mixed, and challenges remain in the move toward bundled payments. Recognition of a fiduciary relationship avoids the critiques lobbed at Medicare Advantage and RACs because it relies on the provider to inculcate cost-containment efforts in her clinical practice and avoids installing third parties between doctors and patients. Finally, CMS’s new proposals may blunt the incentives to rely on more expensive medications, but will likely not eliminate them.

This proposal aligns with the argument that the provider can best determine what procedures are not only medically necessary, but also the most cost-effective. The fiduciary duty regime would serve as an additional or stand-alone way to curb unnecessary Medicare expenses. And it would undoubtedly provide a much-needed limitation on Medicare’s vague, overly broad “reasonable and necessary” standard.

B. The Payer-Provider Fiduciary Relationship

This analysis posits that Medicare’s payer-provider relationship needs fiduciary protection because the relationship matches the existing fiduciary paradigm. The payer-provider relationship meets all six of Professor Frankel’s factors for a legally recognized fiduciary relationship:

- The administration of health care is a service;
- Participating physicians hold discretion and power;
- Providers aim to serve the patient and payer (indeed, Medicare is purchasing services from providers);
- Oversight of physicians’ medical necessity determinations and clinical techniques is burdensome;
- Payers and patients themselves lack expertise about administering health care (which is why payers depend on providers to administer services and bill for them); and
- Other external controls on overtreatment are too weak.


249. See discussion and accompanying notes, supra notes 65–70.
250. See discussion and accompanying note, supra note 70.
251. See discussion and accompanying note, supra note 99.
Beyond the argued-for “financial” fiduciary duty owed by the provider to the patient, other policy reasons demonstrate that Medicare—the payer—needs additional legal protections. These follow below.

1. Extending the Present Fiduciary Relationship

Extending fiduciary protection to Medicare would mark a natural evolution and extension of the doctrine. As Professor Hall has highlighted, courts have not yet imposed liability for a breach of fiduciary duty “based on financial incentives, even though courts recognize the obvious force that fiduciary principles have in doctor-patient relationships and that these principles are generally hostile to financial conflicts of interest.” But treating physicians as financial fiduciaries to patients does not adequately solve the overtreatment problem because it fails to protect the payer, the party truly harmed by overtreatment. Patients may be unaware that they are receiving excessive health care services, or agnostic about receiving them, or may even desire them. As Steven Brill’s narrative shows, in some situations patients are understandably quick to trust providers when they suggest more, or more expensive, care.

Due to the pain and anxiety that often accompany a health emergency, the patient might justifiably change the narrative: overtreatment becomes thoroughness, excess becomes aggressiveness, and expense becomes necessary. Should a patient have to choose between Avastin and Lucentis, he may not have any interest in the relative costs of the drugs, or any duty (or even ability) to ask about cost. The patient may choose a particular drug because she can take it only once a day, whereas she might need to take a cheaper drug twice a day. However, in clinical scenarios where care is questionably necessary, or where the clinical difference between two drugs or procedures is nonexistent and the price differs substantially, the provider’s fiduciary duties to the payer should prevent the health care enterprise from sanctioning and paying for unnecessary treatment. In these scenarios, the Medicare beneficiary’s desire for overtreatment cannot win the day.

In some clinical situations, the interests of the patient and the payer may be diametrically opposed. The patient and physician may actually be aligned in their desires, and the payer adverse. Limiting the provider’s fiduciary duty to

253. Hall, supra note 21, at 504.
255. See Brown, supra note 33 (analyzing price opacity generally).
256. For example, the wishes of a demanding patient are clearly in conflict with the interests of the American taxpayer. See Hafemeister & Gulbrandsen, supra note 190; see also Shannon Brownlee, Overtreated: Why Too Much Medicine Is Making Us Sicker and Poorer 157–58 (2007) (noting of doctors that “when a patient demands a test, they often comply—even when they know the test is not warranted”). See generally Baily, supra note 135.
only the patient may solve some of the overtreatment problem by preventing fraud or the knowing administration of excessive health care, but it does not prevent the provider from choosing unnecessarily expensive treatment options. To be fully effective in preventing overtreatment when choosing between clinical options, the provider must have and satisfy a duty of loyalty to the payer. A provider must be cognizant of the cost-effectiveness of certain procedures and drugs, and not cede decision-making authority to a demanding patient who wants to be overtreated.

Similarly, when the provider is a fiduciary to the patient, that the provider may also be a fiduciary to the payer of the health services is a natural conclusion. The financial duties of care and loyalty that the provider owes to the patient mirror the duties of care and loyalty that the provider should owe to the payer. Given the state of overtreatment in American health care, this extension of the financial duties would offer the payer a potential legal remedy in cases of overtreatment. As Hall and Schneider have pointed out, “unnegotiated, open-ended contracts make patients as vulnerable financially as they are medically.” And patient financial vulnerability—at least in Medicare—quickly becomes payer vulnerability, particularly because each individual Medicare beneficiary is responsible for so little of his own health care bill.

2. Addressing Medicare’s Monitoring Problems

The fiduciary relationship has been applied to the patient-provider relationship because “sick people are singularly ill-situated to monitor the exercise of medical discretion.” And without adequate monitoring, the central threat to the relationship—self-dealing—must be countered by extra protection. Like in other industries, “[s]elfishness-suppressing requirements—fiduciary obligation, duties of good faith, and other cooperation-favoring principles—are the law’s classic response to such monitoring problems.” Just as the patient cannot appropriately monitor the provider, Medicare’s monitoring failure may lead to overtreatment based on inefficient care.

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257. Comparatively, patients already enjoy extensive legal protection. A patient harmed by a provider can turn to medical malpractice litigation for recompense. But for a payer, few remedies—if any—exist. Previous work on application of the fiduciary metaphor has dealt extensively with clinical situations that harm the patient, but the availability of other remedies for the patient, like medical malpractice, make the debate as to whether or not the provider-patient relationship is a fiduciary one seem almost superfluous.

258. Hall & Schneider, supra note 20, at 681 (suggesting that fiduciary law should apply to the costs that hospitals and physicians charge to patients).

259. See Brill, supra note 5.


261. Id. In a number of situations, relying on patient information and consent is not adequate to protect the patient’s wishes. See Mehlman, supra note 175, at 44–45.
As others and I have argued, the structure and history of Medicare make it uniquely unable to adequately contain its own costs. Most alarmingly, Medicare cannot cut or limit coverage for expensive procedures or drugs based solely on cost-effectiveness grounds. This has generated frequent criticism of its coverage determination process. Further, Medicare often serves as a lightning rod for political debate and attention, and any attempts to make the program more cost-effective or to limit coverage draw fierce political opposition.

Medicare also suffers from the same challenges as the health care enterprise more generally. Specifically, government officials implementing the reimbursement regulations may lack the expertise and information possessed by individual providers. In fiduciary terms, the difference in skill level between the principal (Medicare) and its agent (the provider) is problematic. This “skill deficit that prompted the principal to engage the agent renders the principal vulnerable to abuse by limiting the principal’s ability to monitor the agent.”

Medicare lacks the dexterity, foresight, and resources to adequately police its participating providers in a way that eliminates or neutralizes the overtreatment threat. Some of these challenges are endemic to the insurance industry generally, and others seem to have been created by Medicare itself.

3. Neutralizing the Threat of Self-Dealing

In addition to its inability to monitor providers, Medicare is threatened by provider self-dealing. Although alternative reimbursement mechanisms seek to reform the system, Medicare still links a substantial portion of its reimbursements to providers to the amount of services or drugs—or the expense of those services or drugs—that they provide. Without an adequate counterweight, even the most honest and well-meaning providers are enticed to prescribe and administer increasingly expensive drugs and procedures.

However, the problem is too entrenched for a change to only the reimbursement structure to solve it. As Sandeep Jauhar argued in his book *Doctored*, if Medicare and regulators generate a new reimbursement mechanism that limits some overtreatment, providers will find a new way to increase their profits based on existing loopholes. From his perspective, the

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262. *See* Nicholas Bagley, *Bedside Bureaucrats: Why Medicare Reform Hasn’t Worked*, 101 GEO. L.J. 519 (2013); *see also* Buck, supra note 11, at 1270–82; Fox, supra note 15.

263. *See also* Buck, supra note 11, at 1270–82; Fox, supra note 15. *See generally* Bagley, supra note 262.

264. Kinney, supra note 114, at 1500.

265. *See* Buck, supra note 11, at 1270–82.

266. Sitkoff, supra note 170, at 199.

267. *See* discussion and accompanying note, supra note 262. Indeed, Medicare is working to try and reverse providers’ incentives. *See* HEALTH CARE ADVISORY BD., supra note 195.

268. *See* discussion and accompanying notes, supra Part I.A.

269. *See* JAUHAR, supra note 7, at 96–97.
problem is trust: payers need a legal paradigm that demands and expects trust from its providers. Simply changing reimbursement policies may fall short, so a fiduciary solution focused on addressing this trust gulf seems particularly appropriate.

4. A Flexible Theory for Unforeseen Contingencies

Because the enrollment agreement for a provider joining Medicare resembles a contract between the provider and the federal government, one might think that this agreement establishes a contractual relationship between the federal government and the provider, and that it is therefore unnecessary to import fiduciary duties into the provider-payer relationship. However, multiple courts have formally concluded that the agreement is not a contract.

Accordingly, a flexible and robust duty of loyalty could apply to the relationship. Whether or not the provider agreement between the Medicare program and the participating provider is a contract, the parties cannot account for certain contingencies when they enter into the agreement. As a result, guidance to providers requires that they only bill for care that is “reasonable and necessary.” But Medicare has limited ability ex ante to determine what is reasonable and necessary, largely because the provider has all the expertise and discretion—and even access to the patient—in the patient’s moment of need. As Professor Frankel has noted, recognition of the fiduciary relationship is appropriate particularly when a contractual relationship is infeasible:

[E]ven if such contractual arrangements were feasible, the transaction costs involved in drawing up a detailed prior agreement covering all possible discretionary uses of power over the life of the relation would not only be enormous, but also would probably exceed the benefits of the proposed relation.

Not only is the principal—Medicare—unable to “spell out in advance precisely what the agent should do in all possible future circumstances,” but also “the very purpose of retaining an agent with expertise is undermined if the agent is


272. For instance, these contingencies include what specific treatment plans or procedures will be administered. Medicare cannot effectively limit, or specify, which plans or procedures are appropriate for particular patients before the medical examination.

273. See Health Insurance Claim Form, supra note 83.

274. Frankel, supra note 160, at 813.
not given room to apply that expertise on behalf of the principal to changing conditions.\footnote{275} This situation calls for a provider-payer fiduciary relationship.

\textbf{C. Judicial Precedent}

Fiduciary principles have not been explicitly imported in other health care contexts, including the fraud context. Courts have grappled with whether providers can be fiduciaries to the Medicare program, but have not recognized such a relationship. In one of the seminal federal district court decisions developing the reach and contours of the Anti-Kickback Statute,\footnote{276} the court discussed the applicability of the fiduciary argument to various health care relationships, but ultimately dismissed the plaintiff’s argument:

While there appears to be no basis for a fiduciary relationship between Dr. Neufeld and the United States Department of Health and Human Services (“HHS”) or between Dr. Neufeld and the Ohio Department of Human Services, Office of Medicaid (“ODHS”), there certainly are elements of a fiduciary relationship between Dr. Neufeld and his patients.\footnote{277}

The court dismissed the breach of fiduciary duty allegations brought by the U.S. government—claims tacked on to alleged violations of the False Claims Act.\footnote{278} In reaching a result similar to \textit{Neufeld}, a second district court noted that the “Medicare/Medicaid statute does not unambiguously state that the doctors have assumed a fiduciary relationship towards the United States.”\footnote{279} After acknowledging that “[i]t is undisputed that the typical doctor-patient relationship contains elements of a fiduciary relationship,” the court reiterated that “the Medicare/Medicaid statute does not provide that the funds and the government are included in that relationship, and that the doctors owe duties of loyalty to the funds and the government as well as to their patients.”\footnote{280}

But these dismissals of common law actions based on breaches of fiduciary duty do not provide a complete picture. The argument that providers are fiduciaries to Medicare has arisen repeatedly in \textit{sentencing} for health care fraud offenses. Indeed, under the federal regime and the U.S. Sentencing Guidelines, judges must increase the sentences of individuals found guilty of various health care fraud offenses if they occupied a position of trust.\footnote{281} Numerous courts have grappled with the fiduciary duty issue in cases involving

\footnotesize{\textsuperscript{275} Sitkoff, supra note 170, at 199.\textsuperscript{276} See 42 U.S.C. § 1320a-7(b) (2012).\textsuperscript{277} United States v. Neufeld, 908 F. Supp. 491, 500 (S.D. Ohio 1995) (internal citation omitted).\textsuperscript{278} Id.\textsuperscript{279} United States v. Kensington Hosp., 760 F. Supp. 1120, 1132 (E.D. Pa. 1991).\textsuperscript{280} Id.\textsuperscript{281} U.S. SENTENCING COMM’N, GUIDELINES MANUAL 3B1.1(c) (2008).}
physicians convicted under America’s robust criminal fraud statutes.\textsuperscript{282} The question has been whether the provider occupied a position of trust vis-à-vis Medicare, with a number of federal circuits holding that “health care providers who defraud Medicaid or Medicare may be subject to the abuse-of-trust enhancement.”\textsuperscript{283} Defendants subject to this enhancement have included facility directors,\textsuperscript{284} psychologists,\textsuperscript{285} ambulance company owners,\textsuperscript{286} and—relevant to this analysis—physicians.\textsuperscript{287}

This conclusion is, perhaps, unremarkable.\textsuperscript{288} After all, physicians occupy a position of trust, unlike the role one would ascribe to sellers in other industries. One court discussed the importance of trust\textsuperscript{289} in the medical enterprise—not only the trust between physicians and patients, but also the trust between providers and federal health care programs\textsuperscript{290} (and, by implication, taxpayers). The court noted, “[I]n a professional medical practice, trust between patient and physician is essential and . . . the government as insurer depends upon the honesty of the doctor and is easily taken advantage of if the doctor is not honest.”\textsuperscript{291} In other words, both the patient and payer are in precarious positions when the patient is wheeled into the emergency room.

At least one circuit has ruled differently on the position-of-trust question for sentence enhancement. The Eleventh Circuit held that a Medicare provider “does not occupy a position of trust vis-à-vis Medicare.”\textsuperscript{292} In that case, United States v. Garrison, the Eleventh Circuit noted that “arm’s-length business relationships are not available for the application” of the abuse-of-trust enhancement.\textsuperscript{293} The court found it important that the defendant reported to a fiscal intermediary to “review and to approve requests for Medicare reimbursement before submitting those claims to Medicare for payment.”\textsuperscript{294} Indeed, “[b]ecause of this removed relationship to Medicare, plus [the fiscal intermediary’s] review . . . , [the defendant was] not directly in a position of

\begin{thebibliography}{99}
\bibitem{283} United States v. Hayes, 574 F.3d 460, 480 (8th Cir. 2009) (listing cases).
\bibitem{284} United States v. Bolden, 325 F.3d 471, 478 (4th Cir. 2003).
\bibitem{285} United States v. Hoogenboom, 209 F.3d 665 (7th Cir. 2000).
\bibitem{286} United States v. Gieger, 190 F.3d 661, 665 (5th Cir. 1999).
\bibitem{287} United States v. Ntshona, 156 F.3d 318, 321 (2d Cir. 1998) (“We adopt the view of the other circuits presented with this issue and hold that a doctor convicted of using her position to commit Medicare fraud is involved in a fiduciary relationship with her patients and the government and hence is subject to an enhancement under 3B1.3.”) (emphasis in original); \textit{see also} United States v. Adam, 70 F.3d 776, 782 (4th Cir. 1995) (upholding enhancement for physician accused of kickback violations).
\bibitem{288} In a recent work, Max Mehlman argued “[t]hat the law should regard physicians as fiduciaries for their patients would seem to be indisputable.” \textit{See} Mehlman, \textit{supra} note 175, at 2.
\bibitem{289} \textit{See} Hall, \textit{supra} note 21, at 477–82 (noting the value and therapeutic benefit of trust in the patient-provider relationship).
\bibitem{290} United States v. Rutgard, 116 F.3d 1270, 1294 (9th Cir. 1997) (concluding that the doctor must be credited for “services that he rendered that were justified by medical necessity”).
\bibitem{291} \textit{Id.} at 1293.
\bibitem{292} United States v. Mills, 138 F.3d 928, 941 (11th Cir. 1998).
\bibitem{293} United States v. Garrison, 133 F.3d 831, 839 (11th Cir. 1998).
\bibitem{294} \textit{Id.} at 841.
\end{thebibliography}
trust in relation to Medicare.” After concluding that the relationship was “too attenuated,” and noting that the sentence guideline provision “envisons . . . a physician who possesses the expertise to create erroneous medical records and, consequently, fraudulent Medicare reports that are difficult to detect and to question,” the court rejected the enhancement.

Nevertheless, even that court seemed to imply that the sentencing enhancement could be appropriate for physicians because of their expertise and discretion in billing Medicare. In the Eleventh Circuit cases, the defendants were, in Mills, a nurse and businesswoman and, in Garrison, the owners of a home nursing care entity. It appears that the court found the defendants’ professional positions dispositive, which suggests that even the Eleventh Circuit might apply a sentence enhancement to a providing physician.

D. Practical Upsides

As is true of much of the canon of health law and policy, the major challenge accompanying the effort to limit overtreatment in American health care is achieving the right balance between provider autonomy and patient and taxpayer protective legal regulation. The facts and figures on overtreatment belie the claim that the U.S. health care enterprise is over-regulated. The alarming numbers and examples above demonstrate that there is room for increased regulation beyond mere payment reform—or at least room for regulation to rein in the worst excesses. The regulatory challenge is increasing control over the cost of the health care enterprise without eliminating too much valuable provider discretion.

The instant proposal—that the provider owe a fiduciary duty to the Medicare payer—seeks to achieve that balance by adding a mechanism that both limits health care waste and recognizes the sanctity of the provider’s autonomy. The unique enforcement structure of the fiduciary duty helps this proposal avoid the pitfalls of many other cost-containment strategies, such as the criticism that such strategies encourage bureaucrats and insurance companies to make cost-based decisions to the detriment of both providers and patients. And significantly, the fiduciary structure relies on the expertise and

295. Id.
296. Id. at 842.
297. See id.
298. Id. at 833–34.
299. See id. at 841–42 (“In contrast to Garrison’s lack of discretion and inability to produce the fraudulent Medicare reimbursement requests as section 3B1.3 envisions is a physician who possesses the expertise to create erroneous medical records and, consequently, fraudulent Medicare reports that are difficult to detect and to question.”). The court distinguished the different result in Rutgard, emphasizing that the “enhancement was warranted because the ophthalmologist convicted for Medicare fraud abused the trust implicit” in the practice and patient-physician relationship. Id. (emphasis in original).
300. Up to 30 percent of the dollars spent on American health care are wasted. See Buck, supra note 104, at 466 (noting that more than $700 billion annually is wasted within American health care).
judgment of the provider—rather than that of a third party—to determine when the fiduciary duty to the Medicare payer has been discharged.

Requiring providers to owe Medicare a fiduciary duty would seemingly solve, or at least ameliorate, scenarios like the one exemplified by Lucentis and Avastin above. Where the provider is choosing between two drugs with similar therapeutic value and the cost differential outweighs any clinical benefit the patient would receive from the more expensive drug, the provider would owe a fiduciary duty to the Medicare payer to prescribe the less expensive and equally effective alternative. This duty would be a counterweight to Medicare’s powerful incentives for providers to prescribe the more expensive drug in the above clinical scenario. And like any other wronged entrustor, if the provider fails to act as a responsible fiduciary, Medicare would be able to access the common law remedies available following a breach of fiduciary duty—including potentially excluding the offending provider from future Medicare participation.301 Two points remain: (1) how this regime better ameliorates overtreatment as compared to anti-fraud efforts; and (2) how an additional fiduciary relationship for providers reflects the reality of competing forces and pressures within the delivery of American health care.

First, although enforcing the fiduciary duty relationship may face resource-based challenges—including the same challenges that have dogged Medicare enforcement in the anti-fraud context for years302—this new legal tool could improve the regulatory environment by “right-sizing” the remedy for overtreatment. Indeed, a breach-of-duty action carries fewer potential penalties than the draconian penalties that accompany an anti-fraud action under the federal False Claims Act.303

Overtreatment may be structurally insidious, but may also be the product of both a lack of efficient regulation and incentives that encourage providers to provide more expensive care. An action for breach of the duty of loyalty seeks to address the harm through common law remedies, avoiding the massive statutory penalties that accompany violations of the False Claims Act.

And second, should the instant analysis lead to practical change, physicians’ layered professional duties of loyalty— one to the patient and one to the Medicare payer—would resemble the balanced and nuanced ethical

301. Medicare has the legal authority to exclude an entity or individual from the program by either temporarily or permanently revoking the entity or provider’s ability to deliver health care to Medicare beneficiaries. See 42 U.S.C. § 1320a-7 (2012) (listing exclusionary offenses).


303. See 31 U.S.C. §§ 3729–3733 (2012) (providing for statutory penalties up to $10,000, treble compensatory damages, and costs); Buck, supra note 32 (highlighting how the False Claims Act is used to target overtreatment).
duties that govern another profession: law. Lawyers owe duties to clients and other duties, like the duty of candor, to the court. A lawyer’s duty to be truthful to the court, for example, does not diminish her duties to the client.

In the instant proposal, doctors would similarly owe duties to both patients and Medicare’s payers. If and when those duties conflict, the professional must make a judgment, just like the lawyer caught in an ethical conflict between candor to the tribunal and aggressive representation of the client. I suggest here that the patient’s interests would trump the payer’s, unless they are equal or the clinical options are all advisable.

Lawyers do not represent their clients without limitation. If the client is engaged in a crime or fraud, the lawyer may not counsel or assist. If the client wants to lie to or deceive a court or judicial officer, the attorney may not participate in that deception, and may have to disclose the deception to the court or government. Indeed, these “additional” duties—to the tribunal or even to the adversary—are not in the lawyer’s financial or personal interests. These duties complicate the lawyer’s role and nuance their professional decision making. The lawyer, in essence, is undoubtedly a


309. Indeed, these duties often conflict with a lawyer’s desire to win the case or her financial interest to provide as many legal services as the client will pay for.
Doctors should have the same multifaceted fiduciary obligations. Although doctors traditionally owe a duty only to the patient, perhaps, like lawyers, their professional obligations should become more complex and nuanced. Where appropriate—and particularly where providers are administering health care paid for by the American taxpayer—providers should have a duty to be a steward of public resources. In a publicly funded insurance program, where the state depends on the physician’s services, it makes sense to recognize this second duty of loyalty. Pushing the provider to inculcate this value—to be a loyal steward of public resources—addresses the overutilization problem without destroying the provider’s discretion. And this constraint does not place any third parties between the provider and the patient.

As coordinators and deliverers of health care, providers are already gatekeepers of a valuable resource. A number of ethical duties and legal requirements govern their actions, and parties depend on them. The instant analysis merely gives meaning to something Americans may already recognize: when taxpayers entrust participating providers to care for their elderly, those providers must owe a duty of loyalty to those taxpayers. This duty should require physicians to avoid administering excessive and wasteful health care, which will help to ensure the financial viability of the vital Medicare program.

CONCLUSION

American health care providers continue to administer too much care—and care that is too expensive. Now that the ACA has expanded coverage, added much-needed regulation to the insurance industry, and sought to provide consumer-based tools for patients, the central future challenge of health law and policy is the struggle to control cost and utilization. Regulators must strike a delicate balance between respecting the autonomy and discretion of the provider and building an adequate regulatory framework to rein in the worst of the excess.

Somewhat paradoxically, the battles of yesteryear—concerns that managed care will negatively influence providers to administer less health care and that patients need more robust protection—have given way to rampant overtreatment and excess in Medicare and American health care at large. But a viable solution to the challenge may come from the same place that provided an answer to the managed care challenge: fiduciary duty. This Article seeks to

311. See Comment on Rule 3.3, supra note 307 (“Lawyers have a special obligation to protect a tribunal against criminal or fraudulent conduct that undermines the integrity of the adjudicative process.”).
expand the fiduciary relationship and recognize a new duty of loyalty that providers would owe to Medicare payers. The suggestion maintains provider autonomy by relying on the discretion of the doctor, and thus protecting the importance and intimacy of the clinical relationship. Meanwhile, it inserts a much-needed—and potentially overdue—control on the provider to protect public resources. After all, the health of Medicare, just like the patients who rely on it, is worth protecting.