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**Medicare as Technology Regulator: Medicare Policy's Role
in Shaping Technology Use and Access**

April M. Elliott

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MEDICARE AS TECHNOLOGY REGULATOR: MEDICARE POLICY’S ROLE IN SHAPING TECHNOLOGY USE AND ACCESS

April M. Elliott[†]

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I. INTRODUCTION

New technologies can present great hope, but they come with significant costs. Individuals, organizations, and the government regularly confront choices about how best to take advantage of technology. They pin their hopes on the promise of the next big breakthrough while trying to assess the value of new advances, the risks and reliability of using new technologies, and the cost of implementation—all while keeping pace with the latest innovations. Technological advancements, both dramatic and incremental, in communications, warfare, agriculture, transportation, and especially in medicine continue to change modern society in myriad ways.

It is axiomatic that scientific and technological progress drives modern medicine.¹ In the medical context, the push to develop and deploy new technologies ranging from cutting-edge pharmaceuticals to hardware often runs headlong into questions about the value, risks, and costs of new therapies as well as the breadth of public access to those therapies, including which individuals should have access at what stage of treatment.² Decisions

1. For example, the National Institutes of Health (“NIH”), the leading national public medical research agency, describes its purpose as funding research that helps Americans “liv[e] longer and healthier” by supporting “revolutionary ideas.” NIH’s slogan is “NIH . . . Turning Discovery Into Health.” *About NIH*, NAT’L INSTS. OF HEALTH, <http://nih.gov/about/> (last visited Nov. 17, 2011).

2. See U.S. FOOD AND DRUG ADMIN. (FDA), STRATEGIC PRIORITIES 2011–2015: RESPONDING TO THE PUBLIC HEALTH CHALLENGES OF THE 21ST CENTURY (2011), available at <http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/ucm227527>.

about cost, access, and regulation of health care technology are at the core of the Medicare reform debate. This debate implicates closely held values about life, health, choice, and the role of government as well as the strong financial interests of physicians, hospitals, insurance companies, pharmaceutical companies, and others in the health care industry.³

The tension between the promise of new technologies and the challenges inherent in putting those technologies to use permeates the debate about health care policy generally. This is particularly true in the world of Medicare, which as a national health insurance program not only subsidizes health care for millions of Americans and shapes health policy but also determines the kinds of therapies, treatments, and other services that it will fund, and at what level and under what circumstances it will fund them.⁴ Effectively, Medicare's coverage determinations and benefits policies shape millions of Americans' access to types of care by determining how medical technologies can be used, by whom, and in some cases whether providers will adopt the use of new technologies at all.⁵ Medicare regulates technology in obvious ways—for instance, by requiring a transition to electronic medical record keeping—but also in ways that may not be readily considered technology regulation, such as selecting the medical procedures for which it will provide reimbursement.⁶

Substantively, these reform efforts broadly concern three areas: rising costs, access, and quality.⁷ The cost of health care services and the share of federal spending devoted to Medicare have consistently increased since Medicare's inception, growing from 0.7 percent of gross domestic product

htm (discussing goal of and strategies for “effectively oversee[ing] the translation of breakthrough discoveries in science into innovative, safe, and effective products and life-saving therapies for the people who need them most”); U.S. CONG. BUDGET OFFICE (CBO), TECHNOLOGICAL CHANGE AND THE GROWTH OF HEALTH CARE SPENDING (2008), available at <http://www.cbo.gov/ftpdocs/89xx/doc8947/01-31-TechHealth.pdf>.

3. See discussion *infra* Part III.

4. See *Fee Schedule—General Information*, CTRS. FOR MEDICARE & MEDICAID SERVS., <http://www.cms.gov/FeeScheduleGenInfo/> (last modified Feb. 16, 2011).

5. For a discussion of the proposed national coverage determination (“NCD”) for Computed Tomography Angiography (“CTA”), see *infra* Part IV.

6. See discussion *infra* Section III.C and Part IV.

7. See Michael Chernew, Professor of Health Policy, Harvard Medical Sch., *Physician Payment Post SGR* (May 5, 2011) (written testimony to *The Need To Move Beyond the SGR [Medicare Sustainable Growth Rate]: Hearing Before the Subcomm. on Health, H. Comm. on Energy & Commerce* (H. Comm. Hearing on the Need To Move Beyond the SGR), 112th Cong. (2011)), available from *Hearing: The Need To Move Beyond the SGR*, HOUSE ENERGY & COM. COMMITTEE, <http://energycommerce.house.gov/hearings/hearingdetail.aspx?NewsID=8536> [hereinafter *Health Subcomm. SGR Hearing*].

(“GDP”) in 1970, to 1.9 percent in 1990, to 3.6 percent in 2010.⁸ Medicare spending as a share of GDP is projected to continue to grow to 3.9 percent in 2020 and 5.1 percent in 2030.⁹ Medicare spending in fiscal year 2010 is expected to reach \$524 billion, which is fifteen percent of the federal budget and twenty percent of national health care expenditures.¹⁰ This trend has fostered mounting concerns about the viability of Medicare spending in the future and garnered efforts across the political spectrum to rein in Medicare spending or reduce the rate of increase in Medicare spending (known as “bending the [cost] curve”).¹¹ Costs have also increased for individuals (both beneficiaries and non-beneficiaries) and employers who provide health insurance to their employees, feeding debate about the second major issue in Medicare reform: access.

Access is a core concern for Medicare, and as a health insurance provider for the elderly and disabled Medicare has always endeavored to ensure that vulnerable populations have access to health care.¹² This vision for a basic, core level of access to Medicare appears to have quite broad political support,¹³ but there are consistent challenges in defining the contours of Medicare access and determining whether the pool of beneficiaries should be expanded to provide care for more Americans in the face of the rising burden of costs on individuals and employers.

8. *Medicare Spending as a Percent of Gross Domestic Product, Fiscal Years 1968–2010*, in KAISER FAMILY FOUND. (KAISER), *MEDICARE CHARTBOOK 79* (4th ed. 2010), available at <http://facts.kff.org/chart.aspx?cb=58&sctn=169&ch=1796>.

9. *Medicare Spending as a Percent of Gross Domestic Product 2000–2030*, in KAISER, *supra* note 8, at 84, available at <http://facts.kff.org/chart.aspx?cb=58&sctn=169&ch=1806>.

10. *Overview*, in KAISER, *supra* note 8, at 1, available at <http://facts.kff.org/chartbook.aspx?cb=58>.

11. See Peter Orszag, Office of Mgmt. and Budget (OMB), *Medicare Trustees to America: Bend the Curve!*, OMBLOG (May 12, 2009, 5:09 PM), <http://www.whitehouse.gov/omb/blog/09/05/12/MedicareTrusteestoAmericaBendtheCurve>.

12. Upon signing Medicare into law, for example, President Johnson proclaimed: “No longer will older Americans be denied the healing miracle of modern medicine.” *President Lyndon B. Johnson’s Remarks with President Truman at the Signing in Independence of the Medicare Bill, July 30, 1965*, LYNDON BAINES JOHNSON LIBRARY AND MUSEUM, <http://www.lbjlib.utexas.edu/johnson/archives.hom/speeches.hom/650730.asp> (last updated June 6, 2007).

13. See Kaiser, *Kaiser Health Tracking Poll: Public Opinion on Health Care Issues 1* (Apr. 2011), <http://www.kff.org/kaiserpolls/upload/8180-F.pdf> (finding a total of eighty-nine percent of Americans support only minor spending reductions (32%) or no spending reductions at all (57%) to Medicare in order to reduce the deficit); *id.* at 3 (finding sixty-two percent of seniors support keeping the same level of Medicare benefits); see also Phil Galewitz, *Few Seniors Support GOP Plan To Restructure Medicare*, KAISER HEALTH NEWS (Apr. 27, 2011), <http://www.kaiserhealthnews.org/Stories/2011/April/27/kaiser-poll-on-Medicare.aspx> (discussing survey results).

The last major focus of reform is quality of care. Despite devoting a larger share of spending towards health care than other industrialized nations,¹⁴ numerous studies demonstrate that health care outcomes and the quality of care provided in the American health system, on critical measures such as life expectancy, are worse than in other nations.¹⁵ Many health care policy experts and organizations agree that the quality of care can be improved. They further agree that at least some Medicare spending goes towards care that does not improve health outcomes or even provides incentives for unnecessary care.¹⁶ Thus, changes to Medicare policies require both investment in higher quality care and reduction in unnecessary spending.¹⁷

While issues of cost, access, and quality drive efforts to change Medicare policy, proposed reforms often run into stiff resistance. Conflicts over the value of care, the costs of care, and the role of government in shaping access, quality, and costs have consistently proven difficult to resolve. Changes to Medicare policy have significant effects on providers as well as beneficiaries, who collectively are quite active in pushing Congress and regulators to protect their interests.¹⁸ Medicare policy is constantly in flux due to

14. See CHRIS L. PETERSON & RACHEL BURTON, CONG. RESEARCH SERV., RL34175, U.S. HEALTH CARE SPENDING: COMPARISON WITH OTHER OECD COUNTRIES 2–4 (2007).

15. See *id.* at 45–55.

16. See *Medicare Physician Payment Reform: Hearing Before the Subcomm. on Health, H. Comm. on Energy & Commerce*, 112th Cong. 2 (2011) (Internal Memorandum) [hereinafter *Health Subcomm. SGR Hearing Memorandum*] (stating that current Medicare payment policies “reward[] physicians for the volume of services they provide, not value or medical outcomes”).

17. See, e.g., Chernew, *supra* note 7; *Medicare Spending*, DARTMOUTH ATLAS OF HEALTH CARE, <http://www.dartmouthatlas.org/keyissues/issue.aspx?con=1339> (last visited Nov. 20, 2011).

18. For example, of the lobbying organizations in the United States from 1998–2011, the second-highest-spending one was the American Medical Association (representing providers) and fourth-highest was the American Association of Retired Persons (representing beneficiaries) who often lobby on health care, in addition to Social Security and other matters. See Press Release, American Ass’n of Retired Persons (AARP), AARP to Members of Congress: Don’t Cut Medicare, Social Security Benefits (Oct. 12, 2011), available at <http://www.aarp.org/about-aarp/press-center/info-10-2011/aarp-to-members-of-congress-do-not-cut-medicare-social-security-benefits.html>; *Seniors Groups Lobby Super-Committee*, SENIOR MARKET ADVISOR (Aug. 17, 2011), <http://www.seniormarketadvisor.com/Exclusives/2011/8/Pages/Seniors-groups-lobby-supercommittee.aspx> (discussing AARP lobbying Congress on Medicare and Social Security); Ctr. for Responsive Politics (CRP), *Lobbying: Top Spenders*, OPENSECRETS.ORG, <http://www.opensecrets.org/lobby/top.php?indexType=s> (last visited Nov. 16, 2011). Indeed, the top ten highest-spending lobbying organizations for the same period include the American Hospital Association (providers) and Blue Cross/Blue Shield (a private insurance company that provides Medicare Advantage and Medicare Prescription Drug Plans). CRP, *supra*, *The Blues and Medicare*, BLUECROSS

continuous legislative and regulatory changes¹⁹ that often arise in response to pressure from providers or beneficiaries to address new developments in medicine²⁰ and even to adjust prior reform efforts.²¹ But despite the regularity of Medicare policy change, the more significant reform efforts to address the core issues of cost, access, and quality have been sidelined²² or have not been implemented at all due to pressure from providers or beneficiaries.²³

Many of the core debates at issue involve exactly the kinds of difficult decisions we see elsewhere in technology regulation. Health care policy, and Medicare policy specifically, is unique in the degree to which it directly

BLUESHIELD ASS'N, <http://www.bcbs.com/already-a-member/the-blues-and-medicare/> (last visited Nov. 16, 2011). The biggest spender, the U.S. Chamber of Commerce, *see* CRP, *supra*, has also engaged in significant lobbying on Medicare. *See Medicare Reform*, U.S. CHAMBER OF COMMERCE, <http://www.uschamber.com/issues/health/medicare-reform> (last visited Nov. 16, 2011). *See also* Christopher Rowland, *On Health Care, Lobbyists Flex Muscle: Medicare Overruled on Bone Scan Tests*, BOSTON GLOBE (May 31, 2010), http://www.boston.com/news/nation/washington/articles/2010/05/31/on_health_care_lobbyists_flex_muscle/ (describing providers and patient groups successfully lobbying Congress to reverse a CMS payment policy).

19. *See* Timothy Stoltzfus Jost, *Governing Medicare*, 51 ADMIN. L. REV. 39, 44 (1999).

20. *See id.* at 77.

21. *See Health Subcomm. SGR Hearing Memorandum, supra* note 16, at 3. Congress passed the Sustainable Growth Rate trigger, which took effect in 2002 and aimed to rein in Medicare spending. Pub. L. No. 106-113, § 211(b), 113 Stat. 1501, 1501A-348 (1999) (codified at 42 U.S.C. § 1395w-4(f) (2006)). However, with the exception of 2002, Congress has blocked the trigger's mandated cost reductions through legislation. *See Health Subcomm. SGR Hearing Memorandum, supra* note 16, at 3.

22. For example, the annual recommendations of the Medicare Payment Advisory Commission to Congress to reduce costs and improve the quality of care in Medicare are rarely implemented. *See* Ezra Klein, *News Break: How the White House Hopes To Control Health Care Costs*, WASH. POST EZRA KLEIN BLOG (June 3, 2009), http://voices.washingtonpost.com/ezra-klein/2009/06/breaking_how_the_white_house_p.html. While the landmark 2010 Patient Protection and Affordable Care Act ("PPACA") delegated some measure of increased authority to the Commission in the form of a newly established independent board, the Independent Payment Advisory Board ("IPAB"), many health experts have called for even greater authority in order to control costs and improve care. *See* Pub. L. No. 111-148, §§ 3403, 10320, 124 Stat. 119, 489, 949 (2010); sources cited *infra* note 39; *see also* Ezra Klein, *Four Ways To Improve the Medicare Board*, WASH. POST EZRA KLEIN BLOG (Apr. 20, 2011), http://www.washingtonpost.com/blogs/ezra-klein/post/four-ways-to-improve-the-medicare-board/2011/04/13/AFYsasDE_blog.html.

23. For example, while IPAB was included in PPACA, its authority has faced continued political opposition. Robert Pear, *Medicare Panel Meets Bipartisan Opposition*, N.Y. TIMES, Apr. 19, 2011, at A3; Ezra Klein, *Of Course Many in Congress Don't Want To Control Medicare Costs*, WASH. POST EZRA KLEIN BLOG (Apr. 20, 2011), http://www.washingtonpost.com/blogs/ezra-klein/post/of-course-many-in-congress-dont-want-to-control-medicare-costs/2011/04/13/AFDXcwBE_blog.html; *see also* Kathleen Sebelius, *IPAB Will Protect Medicare*, POLITICO (June 23, 2011), <http://www.politico.com/news/stories/0611/57639.html> (defending IPAB from congressional criticism).

affects human life and implicates deeply moral decisions. As a result, health care decision making is often paralyzed by partisan controversy and emotional debate. But examining Medicare policy from the perspective of technology regulation affords a useful framework for assessing the challenges inherent in Medicare reform.

This paper proceeds in Part II by providing a basic overview of Medicare operations and describes the role of Medicare as understood in academic literature. Part III describes the contours of debate in American health care policy generally and Medicare in particular, demonstrating the importance of Medicare policy, the importance of Medicare policy reform, and the significant challenges that Medicare reform efforts face. Part IV analyzes an example of a controversial proposal regarding Medicare coverage determination from a technology regulation perspective. Part V explains the implications from the technology regulation analysis in Part IV for current debates about payment reform in Medicare and ultimately suggests that Medicare shift to a different payment model.

II. MEDICARE OPERATIONS AND REGULATIONS

Medicare is a crucial provider of health care to millions of Americans and is a significant source of income for doctors, hospitals, and other health care providers.²⁴ On one end, Medicare provides medical insurance to eligible Medicare beneficiaries—individuals sixty-five and older, individuals with certain disabilities, and individuals with permanent kidney failure.²⁵ On the other, Medicare reimburses hospitals, physicians, and other providers for their services, often through insurance companies that act as intermediaries.²⁶ Medicare currently includes four programs. Two come from the original Medicare legislation: Part A for inpatient, hospital care, and Part B for outpatient care.²⁷ Congress added the other two parts in the past fifteen years: Part C or Medicare Advantage, which offers inpatient and outpatient care through private insurance companies,²⁸ and Part D for prescription drug coverage (prescription drugs were not previously covered by Medicare).²⁹

24. See generally KAISER, *supra* note 8, available at <http://facts.kff.org/chartbook.aspx?cb=58>.

25. See *Medicare Program: General Information*, CTMS FOR MEDICARE & MEDICAID SERVS., <http://www.cms.gov/MedicareGenInfo/> (last modified Dec. 14, 2005).

26. “Intermediaries” or insurance companies under contract with CMS process payments and claims. See Jost, *supra* note 19, at 44.

27. Social Security Amendments of 1965, Pub. L. No. 89-97, 79 Stat. 286 (codified as amended at 42 U.S.C. §§ 1395c–1395i-5 (2006)).

28. The Balanced Budget Act of 1997 (“BBA”) first introduced Part C. Pub. L. No. 105-33, 111 Stat. 251 (1997) (codified at 42 U.S.C. §§ 1395w-21 to -29 (2006)); Jost, *supra*

The Centers for Medicare and Medicaid Services (“CMS”) is the principal agency charged with administering Medicare, although other agencies within the Department of Health and Human Services (“HHS”), as well as in the Social Security Administration (“SSA”), play a role in Medicare administration.³⁰ CMS organizes its operations in four consortia, which focus on Medicare health plans, Medicare financial management and fee-for-service operations, Medicaid and children’s health operations, and quality improvement.³¹ CMS issues regulations governing providers, such as services covered by Medicare through national coverage decisions, as well as regulations regarding claims processing and eligibility for payment.³² CMS also enrolls beneficiaries and provides beneficiaries with information about their coverage options.³³

But beyond these administrative responsibilities, CMS’s power is relatively limited, especially with respect to policy-making, and there is scant legal scholarship on Medicare institutions. Timothy Stoltzfus Jost, who has written on legal issues in Medicare, describes Medicare as an “impossibly complex and technical regulatory program” that leaves little policy discretion to CMS.³⁴ Jost explains that because Medicare is perceived as a benefits administration institution with little policy-making authority, scholars have largely overlooked Medicare in favor of studying institutions with greater

note 19, at 44. The Medicare Prescription Drug Improvement and Modernization Act of 2003 (known as the Medicare Modernization Act or “MMA”) modified Part C. *See* Pub. L. No. 108-173, § 221, 117 Stat. 2066, 2180–93 (2003) (amending Part C). These plans sometimes include Part D coverage. *See Medicare Benefits*, MEDICARE.GOV, <http://www.medicare.gov/navigation/medicare-basics/medicare-benefits/medicare-benefits-overview.aspx> (last visited Nov. 16, 2011).

29. MMA § 101, 117 Stat. at 2071–152 (codified at 42 U.S.C. §§ 1395w-101 to -152 (2006)).

30. *See generally* Social Security Amendments of 1965, 79 Stat. 286; *see also* Jost, *supra* note 19, at 82–88 (discussing the history of roles of CMS’s precursor agency (the Health Care Financing Administration), the HHS Office of the Inspector General, and Social Security administrative law judges in Medicare administration).

31. *See Overview, CMS Consortia*, CTRS. FOR MEDICARE & MEDICAID SERVS., <http://www.cms.gov/Consortia/> (last modified Mar. 8, 2011).

32. *See, e.g., The CMS Quarterly Provider Update, April 2011*, CTRS. FOR MEDICARE & MEDICAID SERVS., <http://www.cms.gov/quarterlyproviderupdates/emailupdates/itemdetail.asp?itemid=CMS1246822> (last modified Aug. 23, 2011).

33. *See, e.g., Finding Plans*, MEDICARE.GOV, <http://www.medicare.gov/default.aspx> (last visited Nov. 17, 2011) (providing information to potential beneficiaries and current beneficiaries on enrollment, benefits, changing coverage, finding Medicare-eligible providers, etc.).

34. Jost, *supra* note 19, at 65–66.

regulatory power.³⁵ The relatively small amount of legal Medicare scholarship has focused on the (limited) role of judicial review in Medicare policy,³⁶ adjudication of payment disputes,³⁷ payment policies,³⁸ and the difficulties in effectuating reform through existing political institutions.³⁹

However, much of the existing Medicare scholarship focuses on Congress, which is in fact the most active Medicare policy-making institution. Jost argues that Congress excessively micromanages and is “constantly tinkering” with Medicare, and he concludes that Congress should give bureaucrats more discretion in setting Medicare policy to better effectuate the policy goals of increasing quality of care and cost-containment.⁴⁰ Jost and other scholars argue that congressional involvement in Medicare for budgetary and ideological reasons has hampered rational policy-making in Medicare. Thus, they have called for the creation of an independent entity to implement quality enhancement and cost containment policies,⁴¹ a version of

35. *Id.* at 42 (noting that even when scholarship has focused on benefit administration, it has principally been in the area of Social Security). For an example of such scholarship, see, e.g., JERRY L. MASHAW, BUREAUCRATIC JUSTICE, MANAGING SOCIAL SECURITY DISABILITY CLAIMS (1983) (examining the administration of Social Security benefits and its implications for the study of administrative law).

36. See, e.g., Timothy Stoltzfus Jost, *Health Care Rationing in the Courts: A Comparative Study*, 21 HASTINGS INT'L & COMP. L. REV. 639 (1998); Eleanor D. Kinney, *The Role of Judicial Review Regarding Medicare and Medicaid Program Policy: Past Experience and Future Expectations*, 35 ST. LOUIS U. L.J. 759 (1991).

37. See, e.g., Phyllis E. Bernard, *Empowering the Provider: A Better Way To Resolve Medicare Hospital Payment Disputes*, 49 ADMIN. L. REV. 269 (1997); Phyllis E. Bernard, *Social Security and Medicare Adjudications at HHS: Two Approaches to Administration of Justice in an Ever-Expanding Bureaucracy*, 3 HEALTH MATRIX 339 (1993).

38. See, e.g., David M. Frankford, *The Complexity of Medicare's Hospital Reimbursement System: Paradoxes of Averaging*, 78 IOWA L. REV. 518 (1993); David M. Frankford, *The Medicare DRGs: Efficiency and Organizational Rationality*, 10 YALE J. ON REG. 273 (1993); Eleanor D. Kinney, *Making Hard Choices Under the Medicare Prospective Payment System: One Administrative Model for Allocating Medical Resources Under a Government Health Insurance Program*, 19 IND. L. REV. 1151 (1986); Eleanor D. Kinney, *Medicare Payment to Hospitals for a Return on Capital: The Influence of Federal Budget Policy on Judicial Decision-Making*, 11 J. CONTEMP. L. 453 (1985).

39. See, e.g., LEN M. NICHOLS, NEW AM. FOUND., A SUSTAINABLE HEALTH SYSTEM FOR ALL AMERICANS 8 (2007), available at <http://www.policyarchive.org/handle/10207/bitstreams/8826.pdf>; PAUL N. VAN DE WATER, NAT'L ACAD. OF SOC. INS., DESIGNING ADMINISTRATIVE ORGANIZATIONS FOR HEALTH REFORM (2009), available at <http://www.rwjf.org/files/research/vandewater.pdf>; Timothy Stoltzfus Jost, *The Independent Medicare Advisory Board*, 11 YALE J. HEALTH POL'Y L. & ETHICS 21, 22 (2011).

40. Jost, *supra* note 19, at 44.

41. See Jost, *supra* note 39, at 22 (describing push by health policy experts, politicians, and scholars to create IPAB, which was initially named the “Independent Medicare Advisory Board”); David M. Cutler, *Health Reform Passes the Cost Test*, WALL ST. J. (Mar. 9, 2010), <http://online.wsj.com/article/SB10001424052748703936804575108080266520738.html> (describing an independent commission to control Medicare costs as an important method

which was included in the 2010 Patient Protection and Affordable Care Act (“PPACA”).⁴² But providers, lawmakers, and commentators have strongly criticized this approach, expressing concern about abdicating congressional control of Medicare policy to appointed “experts” who will play a large role in determining access to medical services.⁴³

Other scholarship suggests that Medicare regulation is important not only for budgetary reasons and for ensuring quality of care provided through Medicare but also for the administration of private health care in America. Medicare payment rates, for example, can influence payment rates in the private sector,⁴⁴ suggesting that the impact of Medicare coverage determinations extends beyond Medicare beneficiaries and providers to the American health care system more broadly.

Medicare regulation is thus an important component of both national health and budgetary policy. The difficulty in overcoming values conflicts—discussed in Section III.A, *infra*—and pursuing policies that effectively promote quality care, cost containment, and access is evident in both the current structure of Medicare regulation as well as in debates about how to

for bending the cost curve); David Leonhardt, *Rockefeller: The Economists’ Man in the Senate?*, N.Y. TIMES ECONOMIX (Dec. 8, 2009), <http://economix.blogs.nytimes.com/2009/12/08/rockefeller-the-economists-man-in-the-senate> (reprinting a letter from twenty-six “top health economists” at top universities and think tanks to Senate Majority Leader Harry Reid in support of establishing IPAB in order to control costs and improve quality of care by limiting congressional interference); Uwe E. Reinhardt, *A German Import That Could Help U.S. Health Reform*, N.Y. TIMES ECONOMIX (July 24, 2009), <http://economix.blogs.nytimes.com/2009/07/24/a-german-import-that-could-help-american-health-reform/> (describing proposal for board of outside experts to control Medicare costs as “a very big deal”); cf. Henry J. Aaron, *The Independent Payment Advisory Board—Congress’s “Good Deed,”* 364 NEW ENG. J. MED. 2477 (2011), available at <http://www.nejm.org/doi/full/10.1056/NEJMp1105144> (supporting creation of IPAB to avoid congressional interference and describing challenges IPAB faces in overcoming congressional involvement); Sarah Kliff, *Experts Defend Medicare Board*, POLITICO (May 25, 2011), <http://www.politico.com/news/stories/0511/55622.html> (quoting health economists including “notable centrist” Alice Rivlin defending IPAB in connection with a May 2011 congressional hearing).

42. See PPACA, Pub. L. No. 111-148, § 3403(a)(1), 124 Stat. 119, 489–506 (2010); see also *id.* § 10320, 124 Stat. at 949 (changing name of the Board from “Independent Medicare Advisory Board” to “Independent Payment Advisory Board”).

43. See, e.g., Letter from AIDS Action Baltimore et al. to Senator Harry Reid, Majority Leader, U.S. Senate, and Representative Nancy Pelosi, Speaker, U.S. House of Representatives (Jan. 11, 2010), available at https://www.aamc.org/download/113668/data/group_letter_to_house_speaker_and_senate_majority_leader_re_sena.pdf; Joe White, *Getting the “IMAC” Proposal Right: Some Health Care Homework for the Recess*, ROLL CALL (Aug. 4, 2009), <http://www.rollcall.com/news/37522-1.html>.

44. See Kevin J. Hayes, Julian Pettengell & Jeffrey Stensland, *Getting the Price Right: Medicare Payment Rates for Cardiovascular Services*, 26 HEALTH AFFAIRS 124, 124 (2007); MEDICARE RBRVS: THE PHYSICIANS’ GUIDE (P.E. Gallagher, Am. Med. Ass’n. ed., 2000).

improve Medicare regulation. An alternate perspective that examines Medicare regulation—in particular, coverage decisions that directly touch on issues of quality, cost, and access—from the perspective of technology regulation illustrates that many Medicare regulation challenges can be considered technology regulation challenges. Part III examines this perspective.

III. HEALTH CARE AND MEDICARE POLICY: DEBATING VALUES, POLICY ALTERNATIVES, AND TECHNOLOGY

American health care policy is a perennial source of debate and target of reform. Questions of access, cost, degree of government involvement, and quality of care fuel intense debates moored in deeply held values.

One debate centers on aspects of the value of life and health to individuals and to society: the value of providing individuals with choice among treatment options, the value of care that has the potential to prevent life-threatening or life-altering conditions down the road, the value of care that prevents untimely death, and the value of care that prolongs or increases comfort at life's end. These values are difficult to measure, monetize, and balance, but these are exactly the tasks that health care systems, and in particular Medicare, face.

Another values debate concerns the proper role of government in providing services and access to care. To what degree should the government be involved in the provision of care? What is the scope of services for which the government should pay? For whom and to what extent should the government ensure access to care? And what role should the government take in regulating the private health insurance market? The persistent challenge of answering these questions gives rise to the near-constant salience of health care policy in American politics. At times, the health care policy debate is front-and-center, such as during the debate over health care reform in 2010, discussed in Section III.A, *infra*. However, even when health care policy is not at the forefront of national political debate, Congress, the health care lobby, and CMS constantly debate the contours of Medicare regulation.

As these debates play out, another important question emerges: what is the proper role of Medicare as a technology regulator? Unlike the traditional “high-level” public discourse around Medicare regulation, discussed above, the questions raised by considering Medicare as a technology regulator are subtler. However, questions of how to regulate rapidly evolving technologies, manage the costs of new technologies, and regulate access to medical technologies are inherent in debates about Medicare regulation.

A. VALUES CLASH: HALLMARK OF THE HEALTH POLICY DEBATE

As previously described, the values tensions in the health policy debate exist in the context of the three main reform drivers: cost, access, and quality issues. More specifically, when one or more of these three drivers spur reform proposals, values conflicts often shape provider and beneficiary responses to these proposals. With such difficult-to-address values conflicts, and clear provider and beneficiary incentives to protect their own interests, proposals often run into strong resistance even when the proposals respond to significant needs for reform.

Recent Medicare reform debates illustrate these conflicts, including those debates that dominated the 2008 presidential campaign, the 2010 Congressional elections, and much of the first half of the Obama administration during debate over the PPACA. The public, government officials, candidates, members of the medical community and insurance industry, and an array of other interested parties fiercely argued over the role of government in providing access to care, the role of private insurers, and ways to ensure access to quality care while reining in the increasingly large costs of health care on the government, individuals, and employers. Some of the most hotly contested issues centered on the proper role of the government in resolving the direct conflict between the value of life, the amount that the government should pay to provide care that may prolong life, and how such decisions should be made. For instance, the controversies regarding so-called “death panels,” the creation of the Independent Payment Advisory Board (“IPAB”), and more generalized concerns about Medicare “rationing” care nearly derailed critical pieces of health care reform legislation, demonstrating the difficulty in reconciling tensions between the value of life, the proper role of government, and the proper use of public funds.

Opponents of the health care reform bill coined the term “death panels” to criticize provisions that proposed optional end-of-life counseling sessions for seniors.⁴⁵ They characterized such provisions as unwanted and intrusive bureaucratic interference into the highly sensitive affairs of private individuals. Allegations that proposed reforms would establish “death panels” exemplify the extent to which conflicting values impact the health care reform debate. On one hand there is a very strong public sentiment regarding the value of life that individuals and their families should retain full autonomy in making end-of-life decisions and a strong resistance to

45. Jim Rutenberg & Jackie Calmes, *False ‘Death Panel’ Rumor Has Some Familiar Roots*, N.Y. TIMES, Aug. 14, 2009, at A1.

government being involved in such decisions. On the other hand, there is a very pragmatic concern that government funds should be spent on effective, proven treatments, and that decisions about end-of-life care should take into account the cost and projected benefits of that care.⁴⁶ While the health care reform did not include the controversial end-of-life counseling proposal⁴⁷ and included language preventing care from being “rationed,”⁴⁸ end-of-life coverage issues remain highly controversial.⁴⁹

The controversy surrounding the creation of IPAB reveals similar underlying themes and conflicts within the health care debate. Unlike what happened to the end-of-life counseling provision, the final 2010 health care bill did include a version of the Board. The legislation calls for the establishment of an independent board of fifteen health experts from a variety of professional backgrounds to make recommendations for Medicare payment reform which, if not actively opposed by Congress, would go into

46. See, e.g. Ezra Klein, *Is the Government Going To Euthanize Your Grandmother?*, WASH. POST EZRA KLEIN BLOG (Aug. 10, 2009), http://voices.washingtonpost.com/ezra-klein/2009/08/is_the_government_going_to_eut.html; Robert Pear, *Obama Returns to End-of-Life Plan That Caused Stir*, N.Y. TIMES, Dec. 26, 2010, at A1 (discussing the debate over end-of-life counseling including the congressional debate, views of Obama administration officials, research, and interested citizens groups); Darius Lakdawalla et al., *Medicare End-of-Life Counseling: A Matter of Choice*, AEI OUTLOOK SERIES (Am. Enter. Inst., Washington, D.C.), Aug. 2011, <http://www.aei.org/outlook/101070> (describing key issues in the end-of-life counseling debate, including impact on cost of end-of-life care, access to end-of-life counseling, and end-of-life care options).

47. See Foon Ree, *Senators Eliminate End-of-Life Provision, Respond to Charge of 'Death Panels'*, BOSTON GLOBE (Aug. 14, 2009), available at http://www.boston.com/news/nation/washington/articles/2009/08/14/senators_eliminate_end_of_life_provision/; see also Robert Pear, *Obama Returns to End-of-Life Plan That Caused Stir*, N.Y. TIMES, Dec. 26, 2010, at A1 (explaining that the final PPACA did not include the end-of-life counseling provision).

48. PPACA, Pub. L. No. 111-148, sec. 3403, § 1899A(c)(2)(A)(ii), 124 Stat. 119, 490 (2010) (“The [IPAB] proposal[s] shall not include any recommendation to ration health care, raise revenues or Medicare beneficiary premiums under section 1818, 1818A, or 1839, increase Medicare beneficiary cost-sharing (including deductibles, coinsurance, and copayments), or otherwise restrict benefits or modify eligibility criteria.”); see also Sebelius, *supra* note 23 (Secretary of Health and Human Services explaining that the Independent Advisory Board does not have authority to ration care).

49. For example, in January 2011 the Department of Health and Human Services rescinded regulations permitting the inclusion of end-of-life counseling in Medicare visits, despite coverage of such discussions under Bush administration regulations. See Jason Millman, *White House Attempts To Quiet Revived Talk of 'Death Panels'*, HEALTHWATCH, THE HILL'S HEALTHCARE BLOG (Dec. 27, 2010), <http://thehill.com/blogs/healthwatch/health-reform-implementation/135167-white-house-tries-to-smother-new-death-panel-talk> (“[A]n administration spokesman said the regulation . . . is actually a continuation of a policy enacted under former President George W. Bush.”); Robert Pear, *U.S. Alters Rule on Paying for End-of-Life Planning*, N.Y. TIMES (Jan. 4, 2011), <http://www.nytimes.com/2011/01/05/health/policy/05health.html>.

effect.⁵⁰ The President, several members of Congress, and various health policy experts advocated for the provision, asserting that independent experts were better suited to set policies that could effectively contain costs while improving the quality of care provided under Medicare.⁵¹ The proposal faced harsh criticism, however, for giving too much control to unelected and unaccountable “experts” and for suggesting that Congress was ill-equipped to set Medicare policy.⁵² The final provision included in the bill did not go as far as advocates had hoped in providing a mechanism to control Medicare costs based on data and expertise without congressional interference.⁵³ Yet, the provision remains under fire by various members of Congress and others who are concerned that the Board will be unaccountable, will “ration” care, and will not act in the best interest of Medicare and its beneficiaries.⁵⁴ Thus at the core of this conflict are different views on how to best control costs in Medicare to bring Medicare spending to a sustainable level. Ultimately, both supporters and opponents of an independent Medicare board argue that their approach is better for the health of Medicare beneficiaries and the fiscal health of Medicare, but the two sides disagree as to who can be trusted to promote these interests, with supporters looking to independent experts to make data-driven policy changes and opponents favoring greater control by Congress, physicians, and providers.⁵⁵

As both the end-of-life counseling and IPAB debates illustrate, concerns about the government “rationing” care are particularly salient and limit the range of options available for controlling costs in Medicare. One prominent health economist, Uwe Reinhardt, described the tension between the public’s general distaste for policies that “ration” care and the goal of controlling costs in Medicare as a battle between two competing “common sense” beliefs.⁵⁶ Reinhardt speculated that the conflict between these “common sense” beliefs made it nearly impossible to devise a health reform package

50. Sebelius, *supra* note 23.

51. *See* sources cited *supra* note 41; Letter from President Barack Obama to Senators Edward Kennedy and Max Baucus (June 2, 2009), *available at* http://www.whitehouse.gov/the_press_office/Letter-from-President-Obama-to-Chairmen-Edward-M-Kennedy-and-Max-Baucus/.

52. *See, e.g.*, Letter from AIDS Action Baltimore et al. to Senator Reid and Representative Pelosi, *supra* note 43; White, *supra* note 43.

53. *See, e.g.*, Jost, *supra* note 39, at 22; Klein, *supra* note 22; Leonhardt, *supra* note 41.

54. *See, e.g.*, Jost, *supra* note 39, at 22; Klein, *supra* note 23 (discussing criticisms of the Board); Pear, *supra* note 23; Sebelius, *supra* note 23 (addressing criticisms of the Board).

55. *See* Pear, *supra* note 23.

56. Uwe E. Reinhardt, *A ‘Common Sense’ American Health Reform Plan*, N.Y. TIMES ECONOMIX (July 31, 2009), <http://economix.blogs.nytimes.com/2009/07/31/a-common-sense-american-health-reform-plan/>.

capable of cutting government health care expenditures without bumping up against “rationing” fears.⁵⁷ Since these “common sense” beliefs appear impossible to disentangle from values that shape how Americans view the role of government in health care, Reinhart’s discussion supports the inference that the debates about end-of-life counseling and IPAB indicate a broader clash in values that has been and likely will remain a hallmark of health care decision making.

B. CLASHING APPROACHES TO MEDICARE GOVERNANCE: AN EVER-CHANGING POLICY

Most of the running health care policy debates at the federal level center on Medicare. Congress passed major Medicare payment reforms in 1998 and 2003 and has regularly included changes to Medicare payment and coverage policies in annual budget reconciliation bills as well as in the PPACA.⁵⁸ In contrast to many other areas of federal regulation, congressional modification of Medicare is so common that many consider it a viable method for effectuating policy change.⁵⁹

Federal health care policy debates often focus on Medicare because of its significant and expanding share of federal spending, which consistently thrusts Medicare into the center of debates about balancing the budget and reducing the federal deficit.⁶⁰ The major Medicare reforms of the past fifteen years have all included prominent measures at least nominally intended to control costs in Medicare. These measures strive to reform payments to health care providers⁶¹ by cutting payments to physicians (and certain other providers) when the growth rate of payments exceeds the growth rate of

57. *Id.*

58. *See, e.g.*, PPACA, Pub. L. No. 111-148, 124 Stat. 119 (2010); MMA, Pub. L. No. 108-173, 117 Stat. 2066 (2003); Balanced Budget Act (BBA) of 1997, Pub. L. No. 105-33, 111 Stat. 251; Jost, *supra* note 19, at 67–70.

59. *See* Jost, *supra* note 19, at 43; Jost, *supra* note 39, at 22.

60. *See, e.g.*, H. COMM. ON THE BUDGET, THE PATH TO PROSPERITY: RESTORING AMERICA’S PROMISE, FISCAL YEAR 2012 BUDGET (2011), *available at* <http://budget.house.gov/UploadedFiles/PathToProsperityFY2012.pdf> [hereinafter RYAN BUDGET PROPOSAL] (proposing significant changes in Medicare to address the budget deficit).

61. *Compare* BBA, 111 Stat. 251 (setting the Sustainable Growth Rate system to automatically reduce Medicare expenditures when expenditures exceed the target growth rate), *with Health Subcomm. SGR Hearing Memorandum*, *supra* note 16, at 3 (describing repeated congressional action to prevent the cuts called for by the BBA).

GDP.⁶² They also increase the role of independent experts in providing guidance to Congress on how to control Medicare expenditures.⁶³

A number of officials and commentators on both sides of the aisle emphasize that the long-term fiscal health of the nation requires “bending the curve” of Medicare spending (i.e., reducing the growth rate of Medicare costs to more sustainable levels in the medium and long term).⁶⁴ Many cost-cutting proposals, however, run into such strong opposition that supportive lawmakers ultimately drop them.⁶⁵ Recent examples of this phenomenon include proposals for changing the nature and extent of Medicare coverage,⁶⁶ expanding the role of government in making treatment decisions,⁶⁷ and expanding the government’s role in providing coverage.⁶⁸ Other reforms such as reduced physician payments do succeed but receive such harsh backlash upon implementation that they are never fully permitted to take effect; instead, Congress regularly votes to delay implementation of the

62. BBA, 111 Stat. 251; *see also* *Health Subcomm. SGR Hearing Memorandum*, *supra* note 16, at 2.

63. BBA established the Medicare Payment Advisory Commission (MedPAC), which advises Congress on Medicare policy, providing semi-annual reports to Congress with recommendations on a broad range of issues within Medicare. *About MedPAC*, MEDICARE PAYMENT ADVISORY COMM’N, <http://www.medpac.gov/about.cfm> (last visited Nov. 16, 2011).

64. *See, e.g.*, THE NAT’L COMM’N ON FISCAL RESPONSIBILITY AND REFORM, *THE MOMENT OF TRUTH* 36–42 (2010) (calling for significant Medicare funding changes); Karen Davis et al., *Bending the Cost Curve: Focusing Only on Federal Budget Outlays Won’t Solve the Problem*, THE COMMONWEALTH FUND BLOG (Jan. 28, 2011), <http://www.commonwealthfund.org/Content/Blog/2011/Jan/Bending-the-Health-Care-Cost-Curve.aspx>; Orszag, *supra* note 11.

65. *See* Carl Hulse & Jackie Calmes, *G.O.P. Rethinking Bid To Overhaul Medicare Rules*, N.Y. TIMES, May 5, 2011, at A1 (noting that Ryan proposal was effectively dropped from legislative consideration). The PPACA did not adopt end-of-life counseling or the single payer model. *See* PPACA, Pub. L. No. 111-148, 124 Stat. 119 (2010).

66. *See, e.g.*, Michael McAuliff & Sam Stein, *Paul Ryan’s Budget Becomes Bogeyman Uniting Progressives, Democrats*, HUFFINGTON POST (Apr. 25, 2011), http://www.huffingtonpost.com/2011/04/25/paul-ryans-budget-angry-democrats-town-halls_n_853553.html; Jake Sherman & Marin Cogan, *Some in GOP Squirm over Paul Ryan Budget*, POLITICO (Apr. 12, 2011), <http://www.politico.com/news/stories/0411/53075.html>.

67. For example, see the debate over proposals for end-of-life counseling in health care reform, which opponents called “death panels.” *See Palin v. Obama: Death Panels*, THE FACT CHECK WIRE (Aug. 19, 2009), <http://www.factcheck.org/2009/08/palin-vs-obama-death-panels/>.

68. *See* SARA COLLINS ET AL., *THE COMMONWEALTH FUND, AN ANALYSIS OF CONGRESSIONAL HEALTH CARE BILLS, 2007–2008: PART I, INSURANCE COVERAGE* (2009), <http://www.commonwealthfund.org/Content/Publications/Fund-Reports/2009/Jan/An-Analysis-of-Leading-Congressional-Health-Care-Bills--2007-2008--Part-I--Insurance-Coverage.aspx> (finding that a proposal for single-payer health coverage would garner more savings than other models for reform).

cuts.⁶⁹ While there is widespread agreement on the need to ensure quality of care, including access to advanced medical technologies, and control costs, including managing costs associated with technological advances, Congress and CMS have largely failed to implement workable solutions.⁷⁰

1. *Medicare and the Federal Spending Debate*

The annual budget-making process, especially in the summer of 2011, highlights the salience of Medicare in the federal spending debate. House Budget Committee Chairman Paul Ryan's proposal to substantially change the way Medicare provides coverage by reducing the role of the federal government and increasing reliance on private providers largely defined this year's debate about the federal budget deficit.⁷¹ While the House voted to approve the Ryan budget,⁷² the Chairman of the House Committee with jurisdiction over the kinds of Medicare changes included in the Ryan budget stated that he does not intend to even hold hearings on the Ryan reforms.⁷³ The Ryan budget proposal failed to pass the Senate, effectively killing the proposal for the time being.⁷⁴ Not surprisingly, however, Medicare reforms remain hotly contested in the national political discourse, in particular with regards to the debate over the national debt in the summer of 2011.⁷⁵ Like health reform, the proposed changes to Medicare have proven to be a political lightning rod, invigorating lawmakers and voters on both sides of the aisle.⁷⁶

69. See Merrill Goozner, *The Fiscal Times, Medicare 'Doc Fix' Put on Life Support by AMA Lobby*, KAISER HEALTH NEWS (May 6, 2011), <http://www.kaiserhealthnews.org/Stories/2011/May/05/Fiscal-Times-Medicare-Doc-Fix.aspx> ("It never happened. . . . [E]very year, Congress voids the SGR-mandated cuts.").

70. See Cecil B. Wilson, Am. Med. Ass'n, *Statement* (May 5, 2011) (written testimony to H. Comm. Hearing on the Need To Move Beyond the SGR, 112th Cong. (2011)), available from Health Subcomm. SGR Hearing, *supra* note 7; Jost, *The Independent Medicare Advisory Board*, *supra* note 39.

71. See RYAN BUDGET PROPOSAL, *supra* note 60.

72. H.R. Con. Res. 34, 112th Cong. (2011) (budget approved in the House by a vote of 235 to 193).

73. See Hulse & Calmes, *supra* note 65 (quoting Ways and Means Committee Chairman as stating he "had no plans" to consider the Ryan reforms in committee).

74. H.R. Con. Res. 34, 112th Cong. (2011) (budget rejected in the Senate by a vote of 57 to 40).

75. See, e.g., David Rogers, *Senate Rejects Ryan Budget*, POLITICO (May 25, 2011), <http://www.politico.com/news/stories/0511/55721.html> (discussing the Senate "Gang of Six" debt negotiations regarding Medicare); Noam N. Levy & David S. Cloud, *Debt Deal Raises Pressure on Medicare Providers*, L.A. TIMES (Aug. 3, 2011), <http://articles.latimes.com/2011/aug/03/nation/la-na-debt-impact-20110803> (describing debt ceiling compromise enacted Aug. 2, 2011 which will cut payments to Medicare providers if an alternative debt reduction plan is not adopted by the end of 2011).

76. See Hulse & Calmes, *supra* note 65.

2. *Frequent Congressional “Tinkering” with Medicare*

Congress is very active in setting Medicare policy, through both large- and small-scale interventions. In addition to attesting to the salience of Medicare policy for both budgetary and health care policy reasons, the near-constant congressional involvement in Medicare demonstrates two important things. First, making significant fundamental changes to Medicare’s core functions and institutional policy-making processes is very challenging. Second, congressional tinkering with Medicare regulations has frequent and disruptive effects on the provision of Medicare benefits.

As discussed above, Congress has actively shaped Medicare through sweeping legislative provisions, such as the PPACA, MMA, and BBA, smaller provisions tucked into budget reconciliation and omnibus spending bills, as well as through stand-alone legislation.⁷⁷ Members of Congress also use a range of other oversight mechanisms to exert influence over Medicare policy, from holding formal hearings in the various committees with jurisdiction over various aspects of Medicare⁷⁸ to sending letters to CMS weighing in on Medicare regulations.⁷⁹ This level of involvement has provoked criticism that Congress is, in fact, over-involved in Medicare regulation and inhibits rational, expert-driven policy-making.⁸⁰

3. *Resistance to Large-Scale Change: Influence of Beneficiaries and Providers*

Significant changes to Medicare are prone to invoking strong public resistance. Despite regular “tinkering,” changes to the fundamental nature of

77. See, e.g., statutes cited and text accompanying *supra* note 58.

78. In the House, jurisdiction over Medicare is split between the Ways and Means Committee and the Energy and Commerce Committee. See *Committee Jurisdiction*, H. COMM. ON WAYS & MEANS, <http://waysandmeans.house.gov/About/Jurisdiction.htm> (last visited May 8, 2011); *Subcommittees*, HOUSE ENERGY & COM. COMMITTEE, <http://energycommerce.house.gov/subcomms/subcommittees.shtml> (last visited May 8, 2011). The House Budget Committee also addresses Medicare policy in the annual budget. See RYAN BUDGET PROPOSAL, *supra* note 60. The Senate has a similar split in jurisdiction between the Finance Committee and the Health, Labor, Education, and Pension Committee, with the addition of the Special Committee on Aging which does not have primary jurisdiction but can hold hearings, draft legislation, etc. See *Committee Background*, SENATE SPECIAL COMMITTEE ON AGING, <http://aging.senate.gov/about/index.cfm> (last visited May 8, 2011).

79. See, e.g., Letter from Rep. Peter Roskam et al. to Donald Berwick, CMS Administrator (Mar. 11, 2011) (regarding proposed regulations for “short-cycle dispensing” of pharmaceuticals under PPACA); Letter from Rep. Earl Pomeroy et al. to Donald Berwick, CMS Administrator (Aug. 9, 2010) (expressing concerns regarding proposed payment cuts for outpatient physical therapy services); Letter from Rep. Heath Shuler et al. to Kerry Weems, CMS Administrator (Dec. 16, 2008) (requesting that CMS delay a final rule regarding payment of home oxygen suppliers).

80. See discussion *supra* Part II and statutes cited *supra* note 58.

Medicare and to the guarantee of coverage it provides to millions of beneficiaries are widely considered politically infeasible.⁸¹ The American Association of Retired Persons (“AARP”), for example, represents millions of those beneficiaries and consistently advocates to preserve⁸² and, in the case of prescription drug benefits, to expand⁸³ Medicare benefits. The reaction to the Ryan Medicare proposal speaks to this resistance: Republican leadership in the House, despite expressing support for the proposal, dropped its support once it became clear the bill could not pass the Senate.⁸⁴ As Republican supporters of the proposals faced stark criticism, Democrats promptly began describing the proposal as a bid to “end Medicare” and commentators questioned whether the proposal would motivate seniors and baby-boomers approaching Medicare-eligibility to use their votes to oppose the plan and then punish Republicans at the ballot box in the next election cycle. These speculations were shown to carry water when, in a special election for a vacant congressional seat in New York, the claim that Republicans support policies to “end Medicare as we know it” appeared to be largely responsible for significantly cutting the Republican frontrunner’s lead in the polls.⁸⁵

Providers have also opposed large-scale changes to Medicare. Perhaps the clearest example is pressure exerted by providers on Congress to “fix” doctor payments every year to prevent reductions in payment rates.⁸⁶ While the American Medical Association (“AMA”), the preeminent physicians’ organization in the United States, has recently begun to support more

81. For example, a poll published by the Kaiser Family Foundation in April 2011 found that “62 percent of seniors said they wanted Medicare to be left alone with the program continuing to guarantee the same benefits to all enrollees.” Phil Galewitz, *Few Seniors Support GOP Plan To Restructure Medicare*, KAISER HEALTH NEWS (Apr. 27, 2011), <http://www.kaiserhealthnews.org/Stories/2011/April/27/kaiser-poll-on-Medicare.aspx>.

82. See Press Release, Am. Ass’n of Retired Persons, AARP to Members of Congress: Don’t Cut Medicare, Social Security Benefits (Oct. 12, 2011), *available at* <http://www.aarp.org/about-aarp/press-center/info-10-2011/aarp-to-members-of-congress-do-not-cut-medicare-social-security-benefits.html>; Michael Muskal, *AARP to ‘Super Committee’: Hands Off Social Security and Medicare*, L.A. TIMES (Sept. 21, 2011), <http://articles.latimes.com/2011/sep/21/news/la-pn-aarp-super-committee-20110921>.

83. See Jonathan Cohn, *Republicans to AARP: Payback Time*, THE NEW REPUBLIC (Mar. 29, 2011, 5:01 PM), <http://www.tnr.com/blog/jonathan-cohn/85941/house-republican-hearings-aarp-affordable-care-act> (AARP supported the creation of the Medicare Prescription Drug Program in the Medicare Modernization Act of 2003).

84. See Hulse & Calmes, *supra* note 65; *cf.* H.R. Con. Res. 34, 112th Cong. (2011) (budget rejected in the Senate).

85. Raymond Hernandez, *G.O.P. Medicare Plan Shakes Up Race for House Seat*, N.Y. TIMES, May 5, 2011, at A1, *available at* <http://www.nytimes.com/2011/05/06/nyregion/medicare-heats-up-house-race-in-upstate-new-york.html>.

86. See *Health Subcomm. SGR Hearing Memorandum*, *supra* note 16, at 3.

comprehensive payment reform, the AMA's focus is still largely directed at preventing payment cuts.⁸⁷ Similarly, the American Hospital Association is principally focused on protecting or increasing payment rates to hospitals under Medicare,⁸⁸ and it supported legislation that would kill IPAB out of concern that hospitals would lose their ability to prevent cuts to provider payments.⁸⁹ The American Hospital Association has, however, expressed support for raising the Medicare eligibility age, in order to prevent payment cuts to hospitals.⁹⁰

C. TECHNOLOGY REGULATION AS AN ALTERNATE PERSPECTIVE

As discussed above, the Medicare policy debate involves clashing values and approaches to governance characterized by weighty fiscal pressures, a strong public attachment to the core functions of Medicare, a resistance to an increased role for the government in making coverage decisions, and constant congressional tinkering both to address fiscal concerns and to respond to provider and beneficiary interests. And while the lenses of health care policy and budget policy are understandably the most common ways of viewing Medicare policy debates, they often result in the intractable conflicts discussed above. Thus, stepping out of the health and budget policy contexts to examine Medicare policy through the lens of technology regulation provides a useful perspective in addressing hot-button issues in Medicare policy.

There are two ways in particular that Medicare policy comprises a form of technology regulation. First, the policy directly regulates traditional technology matters: the substitution of electronic health records for paper records, the promotion of increased use of information technology, and the consequent challenges of investment in software, training, interoperability,

87. See Wilson, *supra* note 70, at 2; Jost, *supra* note 39, at 23.

88. See, e.g., *Expiring Medicare Provider Payment Provisions: Hearing Before the Subcomm. on Health, H. Comm. on Ways & Means*, 112th Cong. 2 (2011) (statement of Richard Umbdenstock, President and CEO, American Hospital Association) (calling for extension of current Medicare provider payment rates); Press Release, Am. Hosp. Ass'n, Statement of Rich Umbdenstock on President Obama's Debt Reduction Proposal to the Joint Select Committee on Deficit Reduction (Sept. 19, 2011), <http://www.aha.org/presscenter/pressrel/2011/110919-pr-debt-reduction.pdf> (criticizing proposed cuts to provider payments).

89. Susan Ferrechio, *American Hospital Association Backs Bill To Strike Medicare Panel from Health Law*, WASH. EXAMINER BELTWAY CONFIDENTIAL (Oct. 25, 2010), <http://washingtonexaminer.com/blogs/beltway-confidential/2010/10/american-hospital-association-backs-bill-strike-medicare-panel-hea>.

90. Susan Jaffe, *Medicare Eligibility Age Should Go Up, Hospitals Say*, POLITICO (Sept. 8, 2011), <http://www.politico.com/news/stories/0911/63020.html>.

and privacy.⁹¹ Second, Medicare's national coverage determinations indirectly regulate technology by forcing decisions about the adoption and sustained use of certain technologies. The current Medicare reimbursement process requires a separate coverage decision for each new piece of technology available to providers. Therefore, providers often make decisions on whether to adopt new technologies on the basis of Medicare's national coverage determinations, which set the level of reimbursement when using a particular technology and the particular conditions under which it may be used.⁹²

These indirect technology regulation issues are crucial to Medicare policy and benefit administration but may be less likely to be considered technology regulation matters. These types of decisions, however, are effectively technology regulation decisions. A national coverage decision for the use of a particular imaging technology or pharmaceutical therapy can impact which beneficiaries have access to it and under what circumstances, how much providers are reimbursed for the service, and ultimately whether providers determine they can offer the service at all. This kind of decision brings the conflict in values that often characterizes technology and health care decisions to the forefront: it contrasts the promise of new, potentially life-saving technologies with pragmatic decisions about the relative benefit in terms of outcomes and cost of a technology's use compared to other available options.

IV. EXAMINING A RESCINDED PROPOSED NATIONAL COVERAGE DECISION THROUGH THE LENS OF TECHNOLOGY REGULATION

The dispute over Medicare coverage for use of a particular cardiac imaging technology, Computed Tomographic Angiography ("CTA"), demonstrates the value of a technology regulation perspective. In December 2007, CMS proposed a national coverage determination ("NCD") for CTA that would have limited the use of CTA to symptomatic patients in the context of approved clinical trials.⁹³ Both CMS's coverage determination and providers' strong opposition centered on familiar concerns about the appropriate use of new technologies, the importance of ensuring that new

91. See *E-Health General Information Overview*, CTRS. FOR MEDICARE & MEDICAID SERVS., <http://www.cms.gov/EHealthGenInfo/> (last modified Jan. 26, 2011).

92. See *Medicare Coverage Determination Process Overview*, CTRS. FOR MEDICARE & MEDICAID SERVS., <http://www.cms.gov/DeterminationProcess/> (last modified Jan. 28, 2011); see also discussion of a failed proposed national coverage determination *infra* Part IV.

93. See Burt Cohen, *Medicare Reverses Decision To Limit Coverage of Cardiac CT Heart Scans*, ANGIOPLASTY.ORG (March 15, 2008), http://www.ptca.org/news/2008/031502_CT.html.

technologies are put to sound use, and the difficulty in managing the costs of new technologies. The rapid pace of CTA technology's evolution meant that data on effectiveness and risks swiftly became outdated, and the technology had dynamic and difficult-to-predict effects on the approach physicians took to cardiac diagnostics. Also, the costs of CTA equipment were substantial. Ultimately, CMS backed off of the proposed NCD and allowed CTA coverage determinations to be made at the local level.⁹⁴

The conflict itself shows the technological dimensions of Medicare coverage decisions and the interplay between the drivers for reform and values conflicts. The CTA debate suggests that policies that better account for technological advances and efficient incorporation of technologies would be better not only from a technology regulation perspective, but also for addressing Medicare policy goals and values.

A. CMS RATIONALE: IMPROVE PAYMENT EFFICIENCY, REDUCE RISKS, AND ENSURE APPROPRIATE USE OF THE TECHNOLOGY

CMS explained that its proposal to limit Medicare support for CTA was based on data regarding the effectiveness and risks associated with the use of CTA. It was particularly concerned that physicians were performing CTA scans in addition to other cardiac imaging and diagnostic procedures, leading to unnecessary spending without corresponding improvements in treatment as well as increased risks to patient health.⁹⁵ CMS argued that CTA scans were prone to being used as an extra layer of imaging services that in most cases did not add value to other imaging methods or procedures. Under the existing model, physicians had an incentive to offer patients CTA scans, even if they did not actually add value in diagnosing patients or replace other existing services, because Medicare reimbursed providers per scan. CMS was therefore concerned that Medicare was paying for and encouraging unnecessary scans. Additionally, CMS worried that attendant radiation risks to patients from the use of CTA scans were unjustifiable.⁹⁶

94. See Cohen, *supra* note 93 (reporting that by declining to issue a National Coverage Decision, CMS left "current coverage in place," which implicitly means coverage decisions remained at the local and regional level); *Medicare Coverage Determination Process Overview*, CTRS. FOR MEDICARE & MEDICAID SERVS., <http://www.cms.gov/DeterminationProcess/> (last modified Jan. 28, 2011) ("In the absence of a national coverage policy, an item or service may be covered at the discretion of the Medicare contractors based on a local coverage determination (LCD).").

95. See Phurrough et al., *Decision Memo for Computed Tomographic Angiography (CAG-00385N)*, CTRS. FOR MEDICARE & MEDICAID SERVS. (Mar. 12, 2008), <http://go.cms.gov/tNBB0c>.

96. *Id.*

CMS's concerns arose in the context of a trend of increasing utilization of cardiac imaging services, as well as the emergence of data suggesting that more providers were offering more cardiac imaging services because they were well-reimbursed.⁹⁷ In cardiac imaging, Medicare sets prices for reimbursement for very specific technologies and uses, creating significant opportunities for price distortion, especially as changes in technology and clinical practice undermine the assumptions underlying payment rates.⁹⁸ The combination of financial incentives for providers and patients' strong desire for access to cutting-edge technologies exacerbated concerns that such new technologies were prone to excessive use from both a financial and clinical perspective.⁹⁹

Examining data on CTA scans, CMS determined that the benefits did not justify broad use of the technology and thus proposed only paying for CTA scans used on patients with symptoms of angina and risk for coronary artery disease within designated clinical trials.¹⁰⁰ CMS determined this would promote quality goals,¹⁰¹ ensuring both proper use of a new technology and the efficient allocation of Medicare funds.

B. PROVIDER RESPONSE: CTA IS A WORTHWHILE INVESTMENT WITH POSITIVE DYNAMIC EFFECTS ON DIAGNOSTIC ASSESSMENT, IMPROVED ACCURACY, AND REDUCED RISKS

The provider community forcefully opposed CMS's decision. CMS received nearly 700 comments on the proposed NCD, the vast majority of which voiced opposition to the proposal.¹⁰² These comments included letters

97. See Hayes, Pettengell & Stensland, *supra* note 44, at 125 (noting that growth in cardiac services performed in physician offices raises questions about accuracy of Medicare payment levels for such services); *id.* at 131–32 (noting that use of cardiac imaging services increased faster than use of other cardiac services between 1999 and 2004, with services in physician offices increasing most quickly); *id.* (noting that physicians chose to increase in-office cardiac imaging services, but cardiac imaging in other settings did not decrease to offset the increase); *cf.* Uwe E. Reinhardt, *Fees, Volume and Spending at Medicare*, N.Y. TIMES ECONOMIX (Dec. 24, 2010), <http://economix.blogs.nytimes.com/2010/12/24/fees-volume-and-spending-at-medicare/> (describing increased rates of authorization of imaging services by self-referring physicians with financial interests in provision of such services).

98. See sources cited *supra* note 97.

99. See Cohen, *supra* note 93 (“CMS is afraid that everybody’s going to stack tests—that you’d get a CT[A], then a nuclear stress test, then an invasive cath[eterization].”).

100. See Phurrough et al., *Proposed Decision Memo for Computed Tomographic Angiography (CAG-00385N)*, CTRS. FOR MEDICARE & MEDICAID SERVS. (Dec. 13, 2007), <http://go.cms.gov/u7pE80>; Alicia Ault, *CMS Won’t Limit Reimbursement for CT Angiography*, AM. COLLEGE OF EMERGENCY PHYSICIANS NEWS (May 2008), <http://www.acep.org/content.aspx?id=37798>.

101. See Phurrough et al., *supra* note 100.

102. See Ault, *supra* note 100.

from numerous professional medical organizations¹⁰³ and nearly ninety members of Congress.¹⁰⁴ Six national physicians' organizations, for example, asserted that CMS based its findings on outdated metrics, as the technology had developed significantly since the studies were conducted.¹⁰⁵ Opponents of the NCD claimed that the new data demonstrated that CTA scans were now more accurate, less risky to patient health, and capable of replacing existing imaging services.¹⁰⁶ Providers asserted that the newer CTA technology had become "the clinical standard for diagnosing [coronary artery disease]"¹⁰⁷ and was "advancing every month."¹⁰⁸ They argued that CMS relied on data from far less advanced technology—four-, eight-, and sixteen-slice imaging—whereas sixty-four-slice and higher had become the standard,¹⁰⁹ and a 320-slice technology was also available on the market.¹¹⁰ Further, providers stated that new data suggested that CTA scans replaced the need for other tests¹¹¹ and thus would both "save money and reduce the number of invasive tests."¹¹² Additionally, providers pointed to data suggesting that the most advanced technology significantly reduced radiation exposure as compared both to prior CTA technology and existing alternative diagnostic tools.¹¹³

It is likely that the significant investment many providers had made in CTA technology partially drove their response. The machines are expensive,¹¹⁴ so smaller providers who had recently purchased the technology in reliance on local coverage rates faced a significant risk of financial loss if

103. *See id.*

104. *See MITA Thanks Congress for CCTA Coverage Plea to CMS*, DIAGNOSTIC & INTERVENTIONAL CARDIOLOGY (Mar. 10, 2008), <http://www.dicardiology.com/article/mita-thanks-congress-ccta-coverage-plea-cms>.

105. Ault, *supra* note 100 (describing comments on the proposed NCD submitted to CMS by the American College of Cardiology, the American Society of Nuclear Cardiology, the American College of Radiation, the Society for Cardiovascular Angiography and Interventions, the North American Society for Cardiac Imaging, and the Society of Cardiovascular Computed Tomography); Cohen, *supra* note 93.

106. *See* Cohen, *supra* note 93.

107. Ault, *supra* note 100.

108. Cohen, *supra* note 93.

109. Ault, *supra* note 100.

110. Cohen, *supra* note 93.

111. *Id.*

112. Ault, *supra* note 100.

113. Cohen, *supra* note 93.

114. For example, in 2005, a 64-slice CT scanner by Phillips cost \$1.5 to \$2 million. *See Brilliance 64-Slice CT Scanner by Phillips*, MEDGADGET CARDIOLOGY/RADIOLOGY (Apr. 4, 2005, 5:04 AM), http://www.medgadget.com/2005/04/brilliance_64sl.html.

they could no longer bill Medicare for CTA scans.¹¹⁵ As had been the case with other payment reforms, there were concerns that the coverage change would make the technology available for use in some settings but not others for pure cost, not clinical, reasons.¹¹⁶ Providers were also able to make the case that the change in payment policy would limit beneficiaries' access to a promising technology.

Providers thus attacked the proposal from cost, quality, and access angles, tapping into values arguments about the promise of cutting-edge technology, the role of physicians in determining the appropriate use of new treatments, and the scientific soundness of CTA technology from clinical use and risk perspectives.

C. LESSONS FROM THE CTA DEBATE: ADVANCES IN TECHNOLOGY
POSE SIGNIFICANT CHALLENGES TO SETTING APPROPRIATE
PAYMENT AND COVERAGE POLICIES

CMS and the provider community's dramatically different perspectives are largely a function of challenges in keeping pace with and predicting how technologies will affect the practice of medicine, combined with Medicare's practice of setting very specific coverage and payment policies. While here CMS dropped the proposed policy, the concerns driving the policy remained unaddressed, such as the risks of payments distorting incentives to encourage unnecessary use of technology and unnecessary spending, and the risk that the side effects would outweigh the benefits of use. CMS did not acknowledge the need for policies to reflect rapidly advancing technologies, nor did it address either the dynamic potential of new technologies to reshape the status quo in patient care or the need to provide some level of security in investments in expensive technologies.

1. *Keeping Pace with New Data*

Perhaps the most apparent lesson applicable to Medicare policy-making is that in order for policies governing technology to address policy goals, they must be responsive to current data. Since CTA technology was developing at

115. This was one of the primary concerns communicated by physicians to members of Congress and congressional aides in order to garner signatures of support for the "Dear Colleague" letter sent to CMS. See *MITA Thanks Congress*, *supra* note 104. Cf. Reed Miller, *CMS Set To Cut Medicare Physician Fees for Cardiovascular Imaging*, HEARTWIRE (Nov. 3, 2009), <http://www.theheart.org/article/1018537.do> (paid subscription) (describing reaction in provider community to cuts proposed in the 2010 Medicare Physician Fee Schedule, including speculation that cardiologists would not be able to afford providing certain CT imaging services in non-hospital settings).

116. See Hayes, Pettengell & Stensland, *supra* note 44; Miller, *supra* note 115.

such a rapid pace when CMS announced its NCD, CMS's decision could not account for CTA's true benefits, costs, and risks. Where risks can counteract or overpower the health benefits of a new technology and costs are paid through public funds, certainly risks and costs must be considered and weighed against the anticipated benefits. The CTA case demonstrates that this can be difficult: because the data no longer accurately reflected the nature of the technology in use, CMS's assessment of the benefits and drawbacks of the use of CTA was flawed.¹¹⁷

While CMS would certainly have been better off grounding its initial decision in more current data, providers' descriptions of the technological advances suggest that "current" is really a moving target.¹¹⁸ Relying on data at any particular time can be risky when the technology is undergoing rapid development. Here, however, it appears that a reasonable approach would have been to base the assessment on the iteration of the technology the industry considered to be "the clinical standard."¹¹⁹ This suggests that one critical element of effective Medicare regulation of medical technology is the ability to keep pace with the most recent data, with an eye towards current industry use and standards. Doing so enables policies to better serve the underlying goals of promoting cost-efficiency and quality. Further, the more accurate the underlying metrics, the less likely policies are to distort provider incentives. Better data use would in turn serve quality goals by reducing unnecessary risks from overutilization, cost goals by reducing unnecessary spending, and access goals by preserving access to the technology in clinically appropriate settings.

2. *Dynamic (and Possibly Distortive) Effects of Coverage Decisions*

The CTA debate also suggests that Medicare policy should account for the dynamic effects new technologies can have on treatment. Because Medicare coverage decisions can incentivize providers to invest in or abandon a particular technology, Medicare decision making must not only keep pace with new data, but it must also account for distortive effects on utilization that payment policies may themselves create. Therefore, policymakers must also be sensitive to inadvertently creating incentives for over- or under-utilization of certain medical technology.

While a key presumption underpinning the current fee-for-service model of payment in Medicare is that providers will only authorize medically useful services, data suggest this presumption does not always hold. In the area of

117. See Ault, *supra* note 100.

118. See Cohen, *supra* note 93 (noting that CTA was "advancing every month").

119. See Ault, *supra* note 100.

imaging, in particular, even indirect financial incentives have been linked to increased imaging services usage.¹²⁰ For example, data have shown that physicians with a financial incentive to perform imaging services (i.e., where they own or lease imaging equipment) are more likely to authorize imaging services than those who do not.¹²¹ Further, while Congress and the Medicare Payment Advisory Commission have been actively involved in the attempt to curtail incentives for overutilization of imaging services stemming from self-referrals, policymakers have found it challenging to keep pace with new fee arrangements that continue to provide incentives for overutilization.¹²²

With CTA, the question of how to encourage productive use of the technology was central to the debate. Risks of overutilization were a concern because of a combination of the payment method (payment at time of service), the trends in increased utilization of diagnostic cardiac services, and the degree to which the promise of cutting-edge technology may generate demand for the technology even if it is not more effective.¹²³ In contrast, providers argued that CTA was a clinically superior option to the status quo and thus would displace technologies whose results were less accurate or that carried higher radiation side effects.¹²⁴ Part of this dispute rested on the issue of the age of the data discussed above. But the heart of this conflict goes to the inability of the Medicare model to set a coverage and payment policy on a very specific service-by-service basis capable of adequately accounting for possible duplicative or substitutive uses while minimizing financial incentives for excessive (or insufficient) utilization. Technologies like CTA have the potential to be used to provide both more efficient and less efficient care, but the payment model is not conducive to properly assessing the full potential impact of new technologies or incentivizing efficient and effective use in lieu of duplicative or even harmful uses.¹²⁵ As discussed in Part V, *infra*, a bundled payment model has the potential to address these concerns.¹²⁶

120. Reinhardt, *supra* note 97 (discussing concerns identified by the Medicare Payment Advisory and Congress regarding self-referrals and utilization rate growth in imaging services).

121. *Id.*

122. *Id.*

123. See CBO, *supra* note 2; see also Reinhardt, *supra* note 97.

124. See Cohen, *supra* note 93.

125. This goes to one of the major critiques of Medicare payment policy from both a cost and quality perspective. The fee-for-service model is prone to incentivizing more care but not necessarily quality care. See, e.g., *Medicare Spending*, *supra* note 17; *Health Subcomm. SGR Hearing Memorandum*, *supra* note 16, at 2.

126. See Reinhardt, *supra* note 97.

3. *Security in Investments*

In addition to demonstrating the need for Medicare policies to keep pace with current data on rapidly changing technologies and account for the dynamic impact of technological advances, the CTA debate demonstrates the need for policies that account for the often significant costs of acquiring and integrating new technologies into medical practices. While CMS was greatly concerned about distorted incentives and unnecessary costs, the sunk costs in new technologies on the provider side helped to drive providers' resistance to the proposed NCD.

For clinics or physicians who had recently invested in CTA technology, the prospect of receiving reduced or even no Medicare payments for CTA services posed a significant threat to their ability to perform diagnostic cardiac imaging services and possibly even the financial viability of their practice.¹²⁷ From a cost and quality perspective, this would not necessarily be a bad outcome if CMS's concerns about distorted incentives and unnecessary provision of services were well-founded (although more current data suggested that the cost and quality concerns were not well-founded). But when clinics close and providers cut back, patients may lose access to health care more generally because these clinics and providers invested in technology they can no longer afford to support. While the impact of a clinic closure in an urban area with numerous provider options for beneficiaries¹²⁸ could largely be limited to the physicians and staff of the clinic, in rural areas with fewer provider options¹²⁹ a clinic closure could have a significant impact on access to care and beneficiaries' ability to see providers of their choice. The degree of impact would necessarily vary according to the number and accessibility of other providers in that particular community, but it is clear that beneficiaries' options could be significantly constrained if policies were changed to make recent investments in technology unworkable.

Moreover, the threat of losing Medicare reimbursement for the use of new technologies could discourage research and development in medical advancements, adversely impacting the quality of patient care in the future.¹³⁰ Certainly this, too, is not an approach Medicare should endeavor to promote.

127. See *MITA Thanks Congress*, *supra* note 104; Miller, *supra* note 115.

128. See *Hospital and Physician Capacity*, DARTMOUTH ATLAS OF HEALTH CARE, <http://www.dartmouthatlas.org/data/topic/topic.aspx?cat=24> (last visited May 8, 2011) (noting that generally there are many more providers per capita in urban areas than in rural areas).

129. See *id.*

130. The Proposed National Coverage Determination would have rescinded coverage for procedures that had previously been approved in local coverage determinations. See *MITA Thanks Congress*, *supra* note 104; Miller, *supra* note 115.

Due to the rapid pace of development, some level of uncertainty in the value of technological investments is unavoidable. However, as was evident in the CTA debate, both providers and beneficiaries gain from investments in promising new technologies, as long as Medicare gives providers some level of security in their ability to recover costs. At the same time, the evolving contours of the benefits, costs, and risks of new technologies caution against incentivizing investment without adequate confidence in the technologies' ability to improve the quality of care or cost-efficiency. Medicare thus faces a real challenge in navigating the uncertainties attendant on new technologies while at the same time promoting high-quality, accessible, and cost-efficient care.

4. *A Balanced Approach*

There are two traditional ways in which Medicare has addressed the sorts of challenges implicated by the CTA debate. CMS has experimented with clinical trials, enabling some beneficiaries and providers to utilize new technologies while learning more about the benefits, costs, and risks associated with the given technology.¹³¹ CMS has also delegated coverage determinations of new technologies to local officials¹³² and has declined to make national coverage decisions unless and until the technology's benefits, costs, and risks are well-established. In effect, CMS allows local and regional Medicare intermediaries and carriers to set coverage policies for services for which CMS has not issued a national coverage determination.¹³³ Thus a Medicare-authorized insurance carrier in Arizona could decide to authorize coverage of a new service while authorized carriers in California could chose not to cover the service, or authorize the service under different conditions than the Arizona carrier.

But both the clinical trial and local coverage approaches run contrary to critical values and policy goals in Medicare. Clinical trials and local coverage decisions lead to inconsistent access to new technologies by providing beneficiaries only in certain areas with federally funded care that is not

131. This is a common approach in both CMS and Congress-driven Medicare policy, as well as in other areas of health and technology regulation, such as with FDA-approved clinical pharmaceutical trials.

132. Local coverage determinations are coverage decisions made by a "fiscal intermediary or a carrier . . . respecting whether or not a particular item or service is covered on an intermediary- or carrier-wide basis." *Local Coverage Determinations*, CTRS. FOR MEDICARE & MEDICAID SERVS., http://www.cms.gov/DeterminationProcess/04_LCDs.asp, (last modified July 12, 2011).

133. *Id.*

available elsewhere, thereby risking underutilization of beneficial technologies as well as wasteful spending on ineffective technologies.

In terms of both policy and values, a preferable resolution to the challenge posed by the significant costs of investing in new technologies strikes a balance between incentivizing national investment in promising technologies, discouraging investment in excessively risky or inefficient technology, and supporting the goal of ensuring broad access to as many promising technologies as possible. Unsurprisingly, finding a policy that adequately encompasses this balancing act is challenging.

Examining the CTA debate through the lens of technology regulation thus suggests three principal areas where Medicare policy should be particularly attentive to technology regulation concerns: (1) grounding coverage decisions in up-to-date information on the benefits, costs, and risks of a given technology; (2) accounting for dynamic effects that coverage policies for advancing technologies can have on medical practice; and (3) promoting smart investments in promising technologies with an eye towards broadly distributed access.

V. IMPLICATIONS OF THE TECHNOLOGY REGULATION PERSPECTIVE FOR MEDICARE REFORM: SHIFT TO A BUNDLED PAYMENT STRUCTURE

The lessons from the CTA debate apply beyond cardiac imaging coverage decisions, coverage decisions of rapidly developing technologies, or even coverage decisions themselves. The whole enterprise of Medicare administration revolves around identifying the technologies to which beneficiaries should receive access, determining the level of provider reimbursement, and deciding which beneficiaries should have access. This is certainly true for decisions related to the use of technology in providing or enhancing patient record-keeping services, such as electronic health records. It is also true for decisions about coverage for and access to prescription drugs and durable medical equipment.¹³⁴ Even determinations regarding the use of general care services not directly tied to technology, such as

134. Certainly in this context the Food and Drug Administration plays a prominent role in shaping what therapies and products are available to the public, but Medicare decisions about what to cover, at what levels, and under what circumstances can still be highly controversial and raise the same issues regarding the proper role of Medicare in shaping access to technology as in other areas. See Andie King et al., *ESA Controversy Continues To Draw Attention*, 36 DIALYSIS & TRANSPLANTATION 462 (2007) (discussing debate over the proper Medicare response, in terms of funding and access, to FDA warnings about the use of erythropoiesis stimulating agents in certain patients with kidney disease).

preventative care consultations, can be seen as essentially decisions that optimize the use of medical technologies. Modern healthcare is inexorably linked with the use of technology, and considering how healthcare policy implicates the use of technology is a necessary aspect to any policy decision.

Medicare's current approach to national coverage determinations on a fee-for-service basis is too rigid to respond to the challenges of effectively administering patient care in a swiftly-changing technological landscape. But a technology-oriented perspective may help Medicare to design policies that are more flexible and comprehensive in defining the scope of access to technologies that Medicare covers. These sorts of policies would promote meaningful improvements to quality, cost-effectiveness, and access. More flexible Medicare policy-making should also help navigate difficult values conflicts by giving providers greater discretion in determining the proper course of treatment, which helps address concerns about the role of the government in determining what treatments are available. For example, a more flexible payment system would (1) incentivize physicians to assess potential courses of treatment based on current research on medical effectiveness as well as comparative costs; (2) enable them to use new, pricier technologies when they are likely to be the most effective approach; and (3) limit incentives to use them if older, less expensive approaches were just as likely to be effective. By ensuring that physicians and their patients retain significant control over evaluating treatment options on a patient-by-patient basis based on current data, a more flexible system would avoid concerns about centralized "rationing" while encouraging more rational payment levels and effective courses of treatment.

Especially in the context of current debates about Medicare policy, these lessons line up with recent efforts to reshape Medicare payment reform by moving towards a bundled payment system.¹³⁵ Under a bundled system, instead of paying for each procedure or service performed, Medicare provides a set payment for treating a particular condition.¹³⁶ A recent hearing before the Health Subcommittee of the House Energy and Commerce Committee on payment reform focused largely on efforts to move away from the fee-for-service payment model.¹³⁷ Proposals included moving towards "a more bundled system, that pays for an episode of care or provides a global

135. See, e.g., Mark McClellan, The Brookings Inst., *Prepared Testimony for the House Energy & Commerce Committee 2-3* (May 5, 2011) (written testimony to H. Comm. Hearing on the Need To Move Beyond the SGR, 112th Cong. (2011)), available from Health Subcomm. SGR Hearing, *supra* note 7; Chernew, *supra* note 7, at 4.

136. See *id.*

137. See *Health Subcomm. SGR Hearing Memorandum*, *supra* note 16.

budget,” which would “allow more flexibility for providers and obviate the need for purchasers (such as Medicare or private insurers) to micromanage payment systems.”¹³⁸ Replacing the fee-for-service model with a bundled payment system would shift the focus of the payment model from the volume of services provided to the quality and efficiency of the care provided. Providers would enjoy wide discretion in allocating the amount per episode of care (whether in the form of a lump sum, per episode payment, or global budget) to best serve the beneficiary. Some advocates of a bundled system propose special incentives for efficient, effective treatment in the form of “quality bonuses,” which reward those who provide excellent care, to be determined against dozens of set performance metrics.¹³⁹ Providers could then make cost-effective determinations, for instance, on whether the use of a new imaging technology is appropriate or whether an older, less expensive technology would provide adequate patient care.

A bundled payment model, if properly designed, would address the three lessons of the technology regulation analysis. First, a bundled payment system would grant providers more flexibility in determining when to adopt new technologies—incentivizing providers to monitor new data on available technologies and base decisions on the most current data. As suggested by the technology regulation analysis, this would promote adoption of new technologies only when medically sound and cost-effective. Second, by moving away from coverage decisions specific to individual technologies, bundled payments would allow providers to account for the dynamic effects payment policies have on new technologies, incentivizing providers to adjust their practices according to efficiency and effectiveness. It would also dramatically reduce, if not completely eliminate, the incentives under the fee-for-service model to “stack” services to increase payment.¹⁴⁰ Lastly, bundled payments would grant providers greater financial security in their decisions to invest in new and often costly technologies. Because providers would not be subject to coverage determinations altering payment rates, they would be incentivized to purchase new technologies only when expected quality benefits and cost-effectiveness justify the expenditure, while being discouraged from investing in unnecessarily risky or redundant technologies.

138. Chernew, *supra* note 7, at 4.

139. *Id.* at 5. Additional funds to cover high-risk patients for whom quality treatment exceeds the lump sum payment would also be available under a bundled payment model. *See id.* at 6.

140. “Stacking” services refers to the practice of performing duplicative procedures in order to receive payment for each service provided. CMS is concerned about this phenomenon. Cohen, *supra* note 93 (“CMS is afraid that everybody’s going to stack tests—that you’d get a CT[A], then a nuclear stress test, then an invasive cath[eterization].”).

Providers across the country would be able to make these determinations based on their medical judgment, the needs of their particular beneficiary pool, and any other relevant factors.

A bundled payment system may also ameliorate the values clashes that accompany Medicare policy decision making in several ways. For example, this model should appeal to libertarian sensibilities by shifting more control over individual treatment decisions to providers and beneficiaries. Similarly, a bundled payment system would limit the government's role in picking winners and losers among different medical technologies and therapy options. Also, by improving the cost-effectiveness of care delivery, more resources would be available to serve a broader patient pool—an outcome that would satisfy people and institutions concerned about the breadth of health care access.

Significant challenges remain in setting bundled payment levels that account for differences in patient populations that may involve higher-than-average costs for treating certain conditions. But by adjusting payment levels over time and determining payment rates based on the condition being treated instead of the individual procedure performed, a bundled payment system can provide incentives for both quality and cost-containment with less direct involvement by CMS, Congress, outside experts, and local Medicare plan administrators in treatment decisions. A bundled payment system thus has the potential to better regulate the use of technology in Medicare while reducing clashes between approaches to governing Medicare by promoting quality care, cost-efficiency, and limiting direct government involvement in treatment options.

VI. CONCLUSION

Analyzing Medicare policy from the perspective of technology regulation affords a useful approach for analyzing Medicare reform proposals. As the CTA debate illustrates, the technology regulation lens calls for increased flexibility in accommodating technological advances, while responding to new data on technological benefits, costs, and risks. It further calls for more comprehensive payment models that better account for the dynamic effects of new medical technologies and treatment strategies—payment models that provide incentives for medically beneficial utilization of new technologies while reducing incentives for overutilization. Lastly, it calls for incentives for smart investment in technology, and greater security in such investments, by affording providers greater control and responsibility for how they use new technologies in their practices. A shift away from the current fee-for-service model in Medicare and towards a bundled payment system can accomplish these objectives by paying providers based on the condition being treated

instead of the particular treatments they administer. In shifting the focus of payment to a patient's condition, the bundled payment system allows providers to determine how best to treat their patients, including when and how to utilize new technologies.

At the same time, a bundled payment system would advance Medicare policy goals that weigh heavily in the national political discourse surrounding Medicare. It would promote cost-effective, quality care while limiting direct government control over patient care. Thus, the technology regulation analysis suggests that a bundled payment system facilitates important Medicare policy goals, while avoiding some of the major obstacles that have prevented other reforms from being effectively implemented.