Roadblock to Progress

How Medicare Impedes Health Care Innovation

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EXECUTIVE SUMMARY

What This Paper Covers

This paper compares how innovation works in health care versus other markets. It explains how the unique structure of the U.S. health care system is largely a result of public policy and provides examples of obstacles, perverse incentives, and poor decisions from government agencies and programs, with a particular focus on Medicare. It concludes by outlining principles for how policy can promote innovation.

What We Found

Medicare's coverage and reimbursement policies increase uncertainty without fostering better evidence, mismeasure the value of health care services, and embed these flaws throughout the health care system. This results in unpredictability, excessive regulatory burden, increased barriers to entry, and misaligned incentives for innovators.

Why It Matters

Innovation can improve the value of goods and services (both quality improvements and cost efficiencies), but innovation does not work in health care the same way as in other markets. The United States needs to improve the quality of health care and lower costs, but government distortions make this harder for the tens of millions of seniors on Medicare as well as the other Americans.

Policy Suggestions

Policymakers should reduce government barriers to health care innovation by keeping in mind that (1) government cannot accurately determine value, (2) consumers should be empowered to decide what they most value, (3) quality and cost are both important considerations for value, (4) coverage criteria should be clear and consistent, and (5) public policy should not unnecessarily increase the risks of innovation.

ROADBLOCK TO PROGRESS: HOW MEDICARE IMPEDES HEALTH CARE INNOVATION

Introduction

Policymakers are generally eager to support medical innovation, but it is necessary to articulate why and how to pursue that goal. Innovation is not an end in itself but rather a means of improving the value provided by the health care system, defined as the ratio of quality to cost.

The need for innovation and improved value in the U.S. health care system is clear. It is well-established that the U.S. spends far more on health care than other developed countries — in terms of economic output, roughly 17 percent versus 9 percent.[1] National health expenditures have grown faster than gross domestic product for decades, increasing their share of the economy further.[2] In part this is due to Americans' unique level of wealth and behavioral factors not directly related to the health care system that nonetheless raise costs.[3] But there are still many shortcomings to address in order to ensure value for each dollar spent. Much of the care delivered in the United States is wasteful (up to $935 billion per year) or even harmful (5 percent to 15 percent of health care interactions lead to serious diagnostic errors).[4] Medication or treatment error rates in the United States are slightly worse than comparable countries on average, despite higher spending levels.[5]

To understand why innovation has not ameliorated these flaws of the U.S. health care system, one should consider the impact of public policy. Some turn reflexively to government action as the pathway to innovation, but doing so often stifles more productive advances from the private sector. Therefore, public policy ought to remove obstacles to private sector innovation. Nowhere is this more important than in Medicare.

1 Organisation for Economic Co-operation and Development, "Understanding Differences in Health Expenditure Between the United States and OECD Countries," September 2022, https://www.oecd.org/health/Health-expenditure-differences-USA-OECD-countries-Brief-July-2022.pdf.

2 Centers for Medicare and Medicaid Services, "NHE Fact Sheet," https://www.cms.gov/research-statistics-data-and-systems/statistics-trends-and-reports/nationalhealthexpenddata/nhe-fact-sheet.

3 Liam Sigaud, "America's Poor Health Outcomes Are Driven by Behaviors — Not Coverage or Access to Care," *Open Health Policy*, September 1, 2023, https://www.openhealthpolicy.com/p/americas-poor-health-outcomes-are.

4 William H. Shrank, Teresa L. Rogstad, and Natasha Parekh, "Waste in the US Health Care System: Estimated Costs and Potential for Savings," *Journal of the American Medical Association* 15, no. 322 (October 2019):1501-1509, https://pubmed.ncbi.nlm.nih.gov/31589283/; David E. Newman-Toker et al., "Diagnostic Errors in the Emergency Department: A Systematic Review," U.S. Department of Health and Human Services, Agency for Healthcare Research and Quality, December 2022, https://effectivehealthcare.ahrq.gov/products/diagnostic-errors-emergency/research#field_report_title_1.

5 Nisha Kurani and Emma Wager, "How Does the Quality of the U.S. Health System Compare to Other Countries?," Peterson-KFF Health System Tracker, September 30, 2021, https://www.healthsystemtracker.org/chart-collection/quality-u-s-healthcare-system-compare-countries/#patient-safety.

The most objective method of determining the value of an item or service is its price. This, in turn, is best determined by the aggregate preferences of consumers as expressed by their willingness to pay for those goods or services. The trade-off between quality and cost, and how new products compare to existing ones, implies that technological change as a form of innovation is not always a net value-add. In economic terms, if the marginal cost of a new medical product exceeds its marginal benefit, then it is generally not worth purchasing.

Properly determining value in the health sector is hobbled by the outsized role of the government. Federal programs, and Medicare in particular, are ill-suited to consider the trade-offs involved. Medicare exacerbates this problem by not using clear and consistent criteria for its coverage decisions, which increases uncertainty for innovators and leaves more room for flawed or arbitrary decision-making. Its misvalued prices tend to reflect bureaucratic, political, and industry preferences rather than economic value, which in turn skew the incentives that innovators face, as they do not have a clear picture of whether their investments will meet federal standards or pay off in the market. Medicare's inability to effectively weigh the costs and benefits of new technologies also leads to inefficiencies within the program and with health care innovators outside the program. It also faces a central dilemma between extensively supporting new technology and controlling costs.

This paper discusses how Medicare in particular harms health care innovation, which dulls improvement in the value of care. It concludes with high-level principles for policymakers to remove artificial policy obstacles and disincentives for innovation.

INNOVATION IN THE HEALTH CARE SECTOR

The Textbook Model vs. Reality

In most of the economy, market competition drives innovation. Consumers play a central role in seeking out goods or services with lower prices or better quality than other options, so producers are incentivized to compete by improving their value on these dimensions. Innovation ideally takes the form of changes that increase product value, such as improvements in business practices or technological design.

Consider the market for cell phones, which did not exist before the 1980s. The first cell phones were bulky, expensive, and of poor quality. Over the next few decades, the value of cell phones improved in terms of call quality, battery life, and new features such as text messaging. Quality improvement occurred alongside a decline in the cost of phones and cell service plans. Eventually smartphones transformed the market with an endless array of internet-connected applications. Innovation in technology and business practices

transformed cell phones from a luxury good to one with nearly universal use. Over decades, public policy also generally liberalized telecommunications in order to encourage competition and consumer choice.[6]

The same dynamic should apply to health care. Technological advances that enable the development of new or improved products — such as drugs, devices, and biologics — can help treat or prevent diseases, which would appeal to many patients.[7] Even when such new products are expensive, they may still improve the lives of people with costly health conditions and be a net benefit to societal welfare. The remarkable progress in treatments and prophylactics for HIV is one such case. Over the course of a few decades, HIV infection went from being a death sentence to requiring an expensive cocktail of medications to being preventable with a daily pill. Incremental innovations over many years made attainable what was once impossible and eased untold amounts of pain and suffering. To achieve this, spending on health care had to increase to access these treatments (i.e., buying new drugs that previously did not exist). But innovation lowered the price of achieving good *health*, which had previously been effectively infinite (i.e., no treatment was available).[8]

Unfortunately, medical innovation does not actually function according to the textbook model outlined above. Health care is incredibly complex in terms of both items and services delivered to patients and its business landscape. As in other markets, health care innovators require sophisticated scientific knowledge to develop and manufacture new products and must meet high standards of safety and effectiveness. More uniquely, consumers have a diminished role in the health care system. Despite consumers being the end users of care, the system by design caters to the decisions of numerous other stakeholders who manage treatment options and financing on behalf of consumers. Innovators must do more than just convince consumers that their products add more value than competitors' as in other markets.

These features of the health care system are mostly due to the government policies that create bad incentives, uncertainty, and higher barriers to entry for innovators. Rather than fostering competition and meeting consumer and patient needs, the government's influence leads to resource allocation in both the public and the private health sectors based on political power or bureaucratic priorities.

6 Jeffrey A. Eisensach and Kevin W. Caves, "What Happens When Local Phone Service Is Deregulated?," Cato Institute, Fall 2012, https://www.cato.org/regulation/fall-2012/what-happens-when-local-phone-service-deregulated#liberalization-and-usage.

7 "Biologics" refers to biological products such as vaccines or gene therapy.

8 Tomas Philipson, "If It Ain't Broke, Don't Fix It," *Forbes*, July 14, 2016, https://www.forbes.com/sites/tomasphilipson/2016/07/14/if-it-aint-broke-dont-fix-it/.

GOVERNMENT DISTORTIONS

Numerous government agencies, programs, and policies impact medical innovation. Below is a non-exhaustive summary of some of the more prominent examples.

Food and Drug Administration

The Food and Drug Administration (FDA) authorizes the marketing and use of new products in the health care system if they are found to be safe and effective for their intended use. It offers expedited review or approval for certain products that offer substantial improvement over existing alternatives (or for which no alternative exists), although this does not account for replication or marginal improvement of existing products. The FDA does not make any specific decisions about coverage or reimbursement by insurance companies or federal health programs on the basis of its approval. FDA approvals also tend to be centralized; it has had limited success in outsourcing review of low-to moderate-risk devices.[9] By contrast, in the European Union, multiple "notified bodies" can approve devices to be placed on the market.[10]

Having a proper set of economic incentives is crucial to encouraging productive innovation. Research and development (R&D) of pharmaceutical products is notoriously costly and time-consuming and does not have a guarantee of success. On average, drug companies spent about one quarter of their net revenues on R&D in 2019, almost double from 2000, but only about 12 percent of drugs entering clinical trials receive FDA approval: 38 new drugs have been approved per year on average between 2010 and 2019.[11] The cost of developing new drugs has also increased over time.[12] Drug companies need some level of certainty that they will recoup the costs of these investments with their new products; otherwise they will be less likely to pursue them. Increased barriers to entry, regulatory uncertainty, or other artificial risk factors from the FDA and other agencies make this process more difficult.

Third-Party Payment

Perhaps the largest and longest-running intervention in the health care system by the federal government is the exclusion of employer spending on health care benefits from taxes. This causes an overreliance on third-party payment for health care services because it encourages

9 Brian J. Miller, William Blanks, and Brian Yagi, "The 510(k) Third Party Review Program: Promise and Potential," *Journal of Medical Systems* 47, no. 93 (2023), https://link.springer.com/article/10.1007/s10916-023-01986-5.

10 John Marshall et al, "The Difference between Approval Processes for Medicinal Products and Medical Devices in Europe," *Ophthalmologica* 244, no. 5 (2021):368-378, https://pubmed.ncbi.nlm.nih.gov/34062546/.

11 Congressional Budget Office (CBO), *Research and Development in the Pharmaceutical Industry*, April 2021, https://www.cbo.gov/publication/57126.

12 According to "Eroom's Law," the cost of developing a new drug doubles roughly every nine years. See Jack W. Scannell et al., "Diagnosing the Decline in Pharmaceutical R&D Efficiency," *Nature Reviews Drug Discovery* 11 (2012): 191-200, https://www.nature.com/articles/nrd3681.

firms to spend more on insurance coverage for their staff, which comes at the expense of taxable wage growth that workers might otherwise use to purchase health care coverage or services directly.[13] Insurance makes sense as a financial instrument for protecting against low probability, high expense events such as catastrophic illnesses or injuries, but Americans have come to rely on their health plans to pay for everything, even routine services.

The prominence of third-party payers makes it more difficult for consumers to reward innovations, as other markets do. Payers do not know how much their enrollees value specific services or treatments, while enrollees have less incentive to conserve resources, as their plans incorporate coverage costs into premiums. This makes services cheaper at the point of delivery but more expensive overall. The current system based on negotiations with insurers rather than direct marketing to consumers means there is less pressure for providers to be efficient or to compete on the basis of value. The result tends to be more overspending on health care.

Regulation and Public Funding of Innovation During the COVID-19 Pandemic

Multiple federal agencies create barriers to innovation through mismanagement, politicization, or an inherent inability to respond to changes in the health care system in a timely manner. The COVID-19 pandemic is a useful case study: In the early days of the pandemic, the Centers for Disease Control and Prevention (CDC) distributed a faulty test kit while it and the FDA restricted other entities from using their own.[14]

Some argue that government actually plays a significant role in supporting innovation, attributing most or all of the credit for the quick development of COVID-19 vaccines to public sector R&D funding.[15] While such spending can be helpful during a crisis, it is important to understand the sheer scale of private sector investment. Taxpayer funding for COVID-19 vaccine research through February 2021 amounted to $19 billion, while the entire budget of the National Institutes of Health, which provides research grants, was $41 billion in 2020.[16] By comparison, R&D by the pharmaceutical industry alone amounted to $91 billion in 2020.[17]

Federal funding is also not a good indicator of support for innovation, as governments tend to spend inefficiently by mismanaging resources or misidentifying priorities. For example, the

13 Michael F. Cannon, "The Original Sin of U.S. Health Policy," Cato Institute, July 24, 2023, https://www.cato.org/study/original-sin-us-health-policy.

14 Scott Gottlieb, *Uncontrolled Spread: Why Covid-19 Crushed Us and How We Can Defeat the Next Pandemic* (New York: HarperCollins, 2021), chapter 7.

15 Richard G. Frank, Leslie Dach, and Nicole Lurie, "It Was the Government That Produced COVID-19 Vaccine Success," *Health Affairs Forefront*, May 14, 2021, https://www.healthaffairs.org/content/forefront/government-produced-covid-19-vaccine-success.

16 CBO, *Research and Development in the Pharmaceutical Industry*.

17 Stephen J. Ubl, President and CEO, PhRMA, letter to the Hon. Elizabeth Warren, March 8, 2022, https://www.warren.senate.gov/imo/media/doc/PhRMA%20response%20to%20Warren%20RFI_030820221.pdf; CBO, *Research and Development in the Pharmaceutical Industry*.

government has devoted billions of dollars to COVID-19 boosters despite low uptake and widespread immunization, indicating they are of low value to consumers despite public subsidies.[18] This illustrates why the private sector and not government policymakers should be the key drivers of innovation and why accurate economic signals are so important to their decision-making. The much-maligned profit motive of private businesses not only incentivizes them to take risks on innovations but also provides insights on the most efficient way to allocate resources based on costs and market demand.

Aside from these examples, the most significant way government influences the health care system — and the focus of the rest of this paper — is the Medicare program. The Centers for Medicare and Medicaid Services (CMS) is the largest payer of health care services and the most significant health care regulator in the country. Its policies also have significant spillovers into the private health care market. Therefore, understanding how Medicare impacts innovation is crucial context for how health care innovation works in general.

HOW MEDICARE STIFLES INNOVATION

Whether a new item or service will be covered and at what price is a central consideration for innovators. Private health insurance plans, at least in theory, make these decisions based on the value of such treatments relative to alternatives. On the one hand, if many consumers demand a particular service, plans could lose customers (or firms could lose employees) if they do not cover it but their competitors do. Providers may also refuse to contract with them if they pay too low a rate. On the other hand, if coverage and payment decisions are not cost-effective and do not add sufficient value to justify their expense, less access may be necessary to maintain profitability. Consumers often bristle at coverage restrictions by insurance companies, but such decisions can help avoid unnecessary or harmful services and conserve resources. For example, providers may wish to furnish services with little evidence of clinical benefit.[19]

CMS's coverage and payment decisions are guided by Medicare's statutory and regulatory policies rather than market forces, and sometimes their role is unclear. Furthermore, CMS's decisions have significant implications for taxpayers and influence the behavior of private plans.

18 Joel Zinberg, "The Bivalent Booster Boondoggle," *Wall Street Journal*, October 24, 2022, https://www.wsj.com/articles/the-bivalent-vaccine-boondoggle-fda-cdc-booster-pfizer-moderna-covid-shots-billions-biden-administration-doses-vials-11666638107.

19 Aaron L. Schwartz, Bruce E. Landon, Adam G. Elshaug, Michael E. Chernew, and J. Michael McWilliams, "Measuring Low-Value Care in Medicare," *JAMA Internal Medicine* 174, no. 7 (2014), https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/1868536

Medicare Coverage Policies

While FDA authorization is often a necessary condition for Medicare payment, CMS ultimately decides what to cover. As part of this, CMS sometimes takes on a similar role to the FDA by determining how products deemed safe and effective for the general population would impact Medicare beneficiaries, who typically have more complex medical needs and are underrepresented in clinical studies.[20] Unfortunately, in practice CMS does a poor job articulating clear, consistent, and effective criteria that new products must meet to achieve coverage.

Current law directs Medicare to cover items and services if they are "reasonable and necessary" for the diagnosis or treatment of an illness or injury, except for those that are restricted by law. (For example, the Medicare statute explicitly excludes dental services and weight-loss drugs from coverage.[21]) In relatively rare cases where a new item or service does not fall within an existing service or benefit category, CMS can issue a National Coverage Determination (NCD) spelling out its policies for the program as a whole. Alternatively, it can defer to contractors to make local or case-by-case coverage decisions based on specific circumstances. These determinations can result in non-coverage altogether or coverage with restrictions. For example, CMS may decide to cover a drug only if manufacturers collect clinical data, called Coverage with Evidence Development (CED).

Although CMS is required to publicize the factors that it considers in issuing NCDs, which are subject to notice and comment, many of its coverage policies lack transparency.[22] CMS's criteria and timeline for responding to NCD requests are unknown, and the number of pending requests was released only after congressional pressure.[23] It is also often unclear when CMS will impose additional requirements under pathways such as CED and when they are satisfied.[24]

While evidence development can be useful in determining whether new technology is worth covering in Medicare, the success of CED NCDs on that front has been questionable.

20 Steven A. Farmer, Lee A. Fleisher, and Jonathan D. Blum, "The Transitional Coverage for Emerging Technologies Pathway — Enhancing Innovation While Establishing Patient Safeguards," *JAMA Health Forum* 4, no. 8 (2023), https://jamanetwork.com/journals/jama-health-forum/fullarticle/2808745.

21 See 42 U.S.C. § 1395(a)(12) and 42 U.S.C. § 1396r–8(d)(2) (as referenced by 42 U.S.C. § 1395w-102(e)(2)), respectively.

22 CMS, *(PROPOSED) CMS National Coverage Analysis Evidence Review*, June 22, 2023, https://www.cms.gov/medicare-coverage-database/view/medicare-coverage-document.aspx?mcdid=34.

23 U.S. Congress, House Committee on Energy and Commerce, letter to the Hon. Xavier Becerra and the Hon. Chiquita Brooks-LaSure, July 14, 2023, https://d1dth6e84htgma.cloudfront.net/NCD_Letterto_HHS_and_CMS_July14_d05e5c2a74.pdf; CMS, "National Coverage Determination (NCD) Dashboard," updated August 23, 2023, https://www.cms.gov/files/document/ncd-dashboard.pdf.

24 Joe Grogan, "Medicare's 'Coverage with Evidence Development': A Barrier to Patient Access and Innovation," *Health Affairs Forefront*, May 1, 2023, https://www.healthaffairs.org/content/forefront/medicare-s-coverage-evidence-development-policy-barrier-patient-access-and-innovation.

Requiring participation in studies or data registries generally fails to generate new evidence.[25] Of the 26 NCDs requiring CED between 2005 and 2022 (out of 348), data collection requirements were formally completed in only three cases, but evidence gathering (or lack thereof) is hardly ever used to limit or terminate coverage.[26] Most CED NCDs simply remain in a "purgatory" of restricted coverage: It takes 11.5 years for a product to be removed from CED on average, and some have remained within that pathway for over 15 years.[27] This uncertainty increases when CMS and the FDA have conflicting approaches. For example, in July 2023, CMS established a data registry for new Alzheimer's drugs, with participation being a condition for payment within CED. But the FDA advised manufacturers to instead participate in a private registry, suggesting that its officials doubted that CMS's data would adequately uncover safety risks.[28]

CMS is attempting to improve the process of covering new devices with the Transitional Coverage for Emerging Technology (TCET) coverage pathway, which would streamline review, increase manufacturer engagement, and provide more certainty in terms of timeline. Alongside this effort, CMS has attempted to clarify its evidence review criteria.[29] It remains to be seen if these changes will meaningfully improve management of coverage determinations, but one disappointing feature of TCET is that it is not expected to be efficient. CMS has estimated that it would accept only up to five newly authorized breakthrough devices annually due to resource constraints, without specifying how it would prioritize these candidates.[30] This is a much slower pace of adopting innovative technology than envisioned by other proposals. For example, a proposed pathway under the Trump administration called Medicare Coverage of Innovative Technologies (MCIT) would have automatically extended coverage to breakthrough devices approved by the FDA for up to four years and could receive permanent coverage based on evidence developed during that time. This policy was finalized in 2021 and repealed by the Biden administration within that same year; 19 such products approved by the FDA in 2022 would have received MCIT coverage had the policy continued.[31]

25 Kathryn A. Phillips, "CMS Coverage with Evidence Development — Challenges and Opportunities for Improvement," *JAMA Health Forum* 3, no. 9 (2022), https://jamanetwork.com/journals/jama-health-forum/fullarticle/2796407; Francis X. Crosson and Rita F. Redberg, "Statutory Authority for Medicare Coverage Decisions — CMS Is an Independent Federal Agency," *JAMA Internal Medicine* 9, no. 183 (2023): 910-912, https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2808075.

26 CMS, *(PROPOSED) Coverage with Evidence Development*, June 22, 2023, https://www.cms.gov/medicare-coverage-database/view/medicare-coverage-document.aspx?mcdid=35; Phillips, "CMS Coverage with Evidence Development."

27 U.S. Congress, House Committee on Energy and Commerce, memorandum to Subcommittee on Health Members and staff, https://d1dth6e84htgma.cloudfront.net/07_18_23_Public_Memo_HE_Hearing_Innovation_and_Medicare_6a20a8c4b2.pdf; Grogan, "Medicare's 'Coverage with Evidence Development.'"

28 Jessica Karins, "FDA Postmarket Requirements For Leqembi Leave Out CMS Registry," *Inside Health Policy*, July 18, 2023, https://insidehealthpolicy.com/daily-news/fda-postmarket-requirements-leqembi-leave-out-cms-registry.

29 Farmer, Fleisher, and Blum, "The Transitional Coverage for Emerging Technologies Pathway."

30 CMS, "Medicare Program; Transitional Coverage for Emerging Technologies," 88 Fed. Reg. 41633 (June 27, 2023), https://www.govinfo.gov/content/pkg/FR-2023-06-27/pdf/2023-13544.pdf.

31 See list of FDA Breakthrough Devices that received authorization in 2022 here: https://www.fda.gov/medical-devices/how-study-and-market-your-device/breakthrough-devices-program. See rule summarizing and officially repealing MCIT here: https://www.federalregister.gov/documents/2021/11/15/2021-24916/medicare-program-medicare-coverage-of-innovative-technology-mcit-and-definition-of-reasonable-and.

Medicare Payment Policies

Medicare's overall method of determining payment amounts for items and services also contributes to severe problems in effectively allocating health care resources. Traditional Medicare operates under a fee-for-service system that largely reimburses health care providers based on the cost and amount of care they furnish. This encourages the unnecessary provision of services with little or no clinical benefit or care in which the risk of harm outweighs its potential benefit: Medicare spent as much as $6.5 billion on such services in 2021, with about 36 percent of beneficiaries receiving at least one such service that year.[32] Increases in the volume and intensity of health services are expected to be a factor in spending growth over the coming decades.[33] Two case studies that demonstrate these incentives involve the Cincinnati Children's Hospital and Duke Hospital Medical Center, which each launched their own efforts to improve quality of care. The hospitals succeeded in reducing patient costs and lengths of stay, but this decreased the Medicare revenue they received per patient, as it meant that they were delivering fewer services to them.[34] Even though such innovations leave patients and payers objectively better off, Medicare financially punishes providers for it.

The prices used in Medicare are also flawed. All federal agencies tend to orient their decisions around rigid timelines and processes rather than organic developments in the market. CMS officials, for example, calculate Medicare payment rates during annual rulemaking using data on input costs. This leaves plenty of room for error because no central planner can possibly possess all the relevant information at any given time. Indeed, not only does this process focus on the supply side rather than the demand side of the equation, but CMS usually uses two-year-old data (that is, 2024 prices are based on 2022 costs). Misvaluing services has real-world consequences in terms of waste (in the case of overpayment) or reduced access to care (in the case of underpayment or no payment).

CMS's administrative method of price-setting, despite its formalism and veneer of objectivity, still manages to insert a great deal of subjectivity into the process. This inherently undermines the predictability of payment policy and leaves the door open to undue influence by powerful incumbent stakeholders who can navigate the complexity of the opaque rulemaking process. Because convincing a relatively small number of government officials can help secure lucrative pay raises for individual providers or products, nearly every agency decision encourages a flurry of lobbying — either to federal officials directly or to Congress to overrule

32 Medicare Payment Advisory Commission, *Health Care Spending and the Medicare Program*, July 2023, https://www.medpac.gov/wp-content/uploads/2023/07/July2023_MedPAC_DataBook_SEC.pdf.

33 Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds, *2023 Annual Report*, Table II.D1, https://www.cms.gov/oact/tr/2023.

34 Marta Podemska-Mikluch and Elise Amez-Droz, "How Medicare Is Hindering Healthcare Innovation, and a Way Forward," Mercatus Center, December 4, 2018, https://www.mercatus.org/research/policy-briefs/how-medicare-hindering-healthcare-innovation-and-way-forward.

CMS. For example, when CMS offers higher reimbursement rates for new innovative items and services, it is allowed even more leeway to make arbitrary decisions in order to promote access. For outpatient services, CMS can overrule its own criteria for determining when and how to apply these extra payments and instead make payment adjustments "as determined to be necessary to ensure equitable payments."[35] For inpatient services, CMS does not need to abide by ordinary fiscal constraints, such as budget neutrality rules, for its add-on payments.[36] Rather than establish clear and consistent guidance for innovators, these rules encourage firms to secure a financial advantage through lobbying and increase government spending without quantifying whether the prices it establishes represent a net value improvement for Medicare.

Cost Considerations

With cost being an important component of value, one would think it would be a factor in CMS's coverage and payment decisions. The practical and political necessity of maintaining a sustainable program and being a good steward of taxpayer dollars should necessitate the same kind of cost-benefit analysis that CMS conducts (albeit imperfectly) in other areas of Medicare policy and that is required in rulemaking. Yet despite the discretion that CMS has in coverage and payment policies, there are limits on its ability to consider costs at all.

CMS generally retains "maximum discretion" to make coverage determinations, according to long-standing legal precedents.[37] However, current law does not explicitly allow CMS to consider cost in such decisions, nor has CMS issued regulations or guidance outlining how it might do so. There have been only irregular references to cost considerations by Medicare officials over the years.[38] Some scholars have argued that the statutory "reasonable and necessary" standard restricts CMS from *openly* considering cost in its coverage decisions but that it continues to play a "hidden role" in internal deliberations, despite the legal requirement for CMS to publicize its coverage criteria. This perspective suggests that CMS approval of coverage on a limited basis may be viewed as a "compromise" to contain the cost of new items and services without denying access to beneficiaries, which may be perceived as rationing care or even directly obstructing innovation.[39] Rather than permitting an open accounting of

35 42 U.S.C. § 1395l(t)(2)(E).

36 New technology add-on payments under the Inpatient Prospective Payment System are exempt from budget neutrality requirements (42 U.S.C. § 1395ww(d)(5)(K)-(L)). Pass-through payments under the Outpatient Prospective Payment System may not, in aggregate, exceed 2 percent of total payments under that system (42 U.S.C. 1395l(t)(6)(D)-(E)).

37 C. Joseph Ross Daval and Aaron S. Kesselheim, "Authority of Medicare to Limit Coverage of FDA-Approved Products: Legal and Policy Considerations," *JAMA Internal Medicine* 9, no. 183 (2023): 999-104, https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2808074

38 Jacqueline Fox, "Medicare Should, but Cannot, Consider Cost: Legal Impediments to Sound Policy," *Buffalo Law Review* 53 (2005-2006): 577-633, https://scholarcommons.sc.edu/cgi/viewcontent.cgi?article=2098&context=law_facpub.

39 Jacqueline Fox, "The Hidden Role of Cost: Medicare Decisions, Transparency and Public Trust," *University of Cincinnati Law Review* 79 (2011), https://scholarship.law.uc.edu/cgi/viewcontent.cgi?article=1043&context=uclr.

how cost factors into its decisions, CMS leaves the public and stakeholders guessing about the role it plays.

Nor can CMS necessarily rectify cases where there is clear evidence of overpayment. For example, CMS pays for most Part B drugs (i.e., drugs that are administered by a health care professional in an outpatient setting) at 106 percent of the average sales price. Although this incorporates market pricing to some extent, it bakes in 6 percent overpayments by Medicare and does not account for factors that impact cost such as rebates and discounts offered to pharmacy benefit managers or federal drug discounts given to hospitals. Yet federal courts have struck down multiple attempts to align Medicare reimbursement of Part B drugs with their costs.[40] One of those cases held that CMS could make only a binary choice to cover an item or service at the statutory rate or not cover it at all.[41] That is, CMS does not have the discretion to decide that it is "reasonable and necessary" to for an item or service at one rate but "unreasonable and unnecessary" to do so at another, higher rate. Conversely, there is also a danger in pursuing cost reduction as the highest priority, independent of economic value. For example, the Part D drug program in Medicare largely contained drug spending through competition among private plans. However, the extension of government price controls under the Inflation Reduction Act is expected to reduce innovation and access in the drug market while perversely encouraging higher launch prices and plan costs.[42]

Spillovers to the Private Market

Medicare's policies directly and indirectly influence the rest of the health care sector as well, including the practices of private plans. Government decisions are imposed rather than negotiated, and they are made independently of market pressures that the private sector faces. But even when these decisions are not directed to the private health care market, other actors still adapt to the artificial rules that Medicare imposes on the entire health care sector.

There is significant alignment in what new products Medicare and private payers will cover (although individual plans in the private market each set their own rules). Both Medicare and commercial insurance take roughly 4.7 years to establish national coverage following FDA authorization on average, but Medicare establishes coding, payment, and local coverage

40 See, for example, Pew Charitable Trusts, "The 'Least Costly Alternative' Approach for Payment of Medicare Part B Drugs," March 10, 2016, https://www.pewtrusts.org/en/research-and-analysis/fact-sheets/2016/03/the-least-costly-alternative-approach-for-payment-of-medicare-part-b-drugs; CMS, "Hospital Outpatient Prospective Payment System: Remedy for the 340B-Acquired Drug Payment Policy for Calendar Years 2018-2022 Proposed Rule (CMS 1793-P)," July 7, 2023, https://www.cms.gov/newsroom/fact-sheets/hospital-outpatient-prospective-payment-system-remedy-340b-acquired-drug-payment-policy-calendar.

41 Ilene Hays v. Kathleen Sebelius, No. 08-5508 (D.C. Cir. 2009), https://law.justia.com/cases/federal/appellate-courts/cadc/08-5508/08-5508-1221815-2011-03-24.html.

42 Joel Zinberg, "The Arrival of Medicare Drug Price Controls: No Cause for Celebration," Paragon Health Institute, September 6, 2023, https://paragoninstitute.org/policy-brief-joel-zinberg-medicare-drug-price-controls-20230906/; Kylie Stengel, Matt Kazan, and Kelly Brantley, "How May the IRA Shift Part D Market Dynamics?," Avalere, August 24, 2023, https://avalere.com/insights/how-may-the-ira-shift-part-d-market-dynamics.

determinations faster.[43] Between 1999 and 2013, private plans' coverage policies were equivalent to Medicare's NCDs roughly half the time, while they were more restrictive and less restrictive, on average, about a quarter of the time each.[44] In other words, while the private market does not always follow Medicare's lead when it comes to covering new technology, government decisions often inform what they will cover.

Medicare payment policies also impact those of private plans, despite having different methods of establishing prices. CMS updates payment rates annually through regulation, and providers have limited options if they think those rates are inadequate. "Non-participating" providers who do not accept assignment (i.e., they do not accept Medicare rates as full payment in all cases) can charge 15 percent over the Medicare-approved amount for a service at most. Providers can also opt out entirely, but few do, as it denies them access to a large patient population.[45] Drug manufacturers face penalties of up to 95 percent of sales revenue for drugs they choose to withdraw from Medicare Part D's drug "negotiation" program.[46]

Insurance plans have less leverage than the federal government does and must negotiate with providers. But oftentimes they simply adopt Medicare's reimbursement rates, which is administratively simpler for providers and payers even given the problems with Medicare rate-setting discussed above. Additionally, Medicare Advantage plans are required to pay at least traditional Medicare rates for services furnished by out-of-network providers.

Researchers also debate whether Medicare prices impact the private market because of cost-shifting — that is, when Medicare reduces its payment rates, providers must compensate for lost revenue by increasing prices for private payers. Some recent studies have found the opposite: Reductions in Medicare reimbursement lead providers to also reduce prices for commercial insurance plans so that they can attract more of their patients.[47]

Given Medicare's large patient population and the high rate of participation in it by health care providers, other Medicare rules and restrictions can influence the private market as well. For example, Medicare's inpatient only (IPO) list forbids payment for certain services if they are furnished outside an inpatient setting. This restricts medical innovations that can allow

43 Sandra Waugh Ruggles et al., "The Need for Accelerated Medicare Coverage of Innovative Technologies: Impact on Patient Access and the Innovation Ecosystem," *Health Management, Policy and Innovation* 7, no. 1, https://hmpi.org/2022/01/17/the-need-for-accelerated-medicare-coverage-of-innovative-technologies-impact-on-patient-access-and-the-innovation-ecosystem/.

44 James D. Chambers et al., "Private Payers Disagree with Medicare over Medical Device Coverage About Half the Time," *Health Affairs* 34, no. 8 (August 2015), https://www.healthaffairs.org/doi/10.1377/hlthaff.2015.0133.

45 Medicare.gov, "Does Your Provider Accept Medicare as Full Payment?," https://www.medicare.gov/basics/costs/medicare-costs/provider-accept-Medicare.

46 Zinberg, "The Arrival of Medicare Drug Price Controls."

47 Roger Feldman, Bryan Dowd, and Robert Coulam, "Medicare's Role in Determining Prices throughout the Health Care System," Mercatus Center, October 8, 2015, https://www.mercatus.org/research/working-papers/medicares-role-determining-prices-throughout-health-care-system.

initially risky procedures to gradually be performed safely in lower-cost outpatient settings. Removing procedures from this list has allowed some services to shift settings and reduce Medicare cost growth.[48] Although the IPO list applies only to Medicare payment, hospitals and commercial payers frequently adopt practices to mirror CMS policy changes, such as by making the outpatient setting the baseline site of service for procedures that are removed from the list. CMS has said that it can do little about these decisions besides urging providers to base site-of-service decisions on clinical appropriateness.[49]

PRINCIPLES FOR ENCOURAGING HEALTH CARE INNOVATION

These Medicare policies reduce health care innovations by increasing uncertainty without fostering better evidence, mismeasuring the value of health care services, and embedding these flaws throughout the health care system. The end result of government intervention in health care is reduced predictability, excessive regulatory burden, increased barriers to entry, and misaligned incentives.

In light of this, policymakers should consider the following principles.

1. The Government Cannot Accurately Determine Value

Despite the conceit that federal officials are best positioned to determine value in Medicare, they are unable to accurately weigh the marginal benefits and costs of covering new services. Difficulties in management are certainly part of the problem (as detailed by point #4 below), but there are also inherent limits to how government can or should attempt to define value. Although value is a key consideration for government programs, it is inherently the end user of a health care service who defines its value, while central planners instead consider factors such as politics or ideology.

Currently, Medicare's outsized influence over the health care sector encourages private actors to piggyback off its decisions rather than pursue innovative payment arrangements or discern market prices. Health care policies should ideally move in the opposite direction: Government decisions should be based on insights from private actors, not the other way around.

48 Joe Albanese, "Reformers Should Look beyond Medicare's Trust Funds," *National Review*, April 14, 2023, https://www.nationalreview.com/2023/04/reformers-should-look-beyond-medicares-trust-funds/.

49 CMS, "Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; New Categories for Hospital Outpatient Department Prior Authorization Process; Clinical Laboratory Fee Schedule: Laboratory Date of Service Policy; Overall Hospital Quality Star Rating Methodology; Physician-Owned Hospitals; Notice of Closure of Two Teaching Hospitals and Opportunity to Apply for Available Slots, Radiation Oncology Model; and Reporting Requirements for Hospitals and Critical Access Hospitals (CAHs) to Report COVID–19 Therapeutic Inventory and Usage and to Report Acute Respiratory Illness During the Public Health Emergency (PHE) for Coronavirus Disease 2019 (COVID-19)," 85 Fed. Reg. 86087 (Dec. 29, 2020), https://www.govinfo.gov/content/pkg/FR-2020-12-29/pdf/2020-26819.pdf.

2. Consumers Should Be Empowered to Decide What They Most Value

The reason markets are able to measure value better than the government can is that they aggregate the preferences of numerous actors based on their behavior (e.g., whether to buy or sell at a specific price point). Ultimately, value is subjective to an extent, because individuals have their own preferences in terms of health needs, risk tolerance, and price sensitivity, among other factors. Enabling them to exercise their power as consumers is an essential component of making sure the market accurately reflects value. A free society also ought to generally trust people to make major decisions about their health care as it does with many complex transactions, such as buying a home.

Government policies currently dictate the delivery or distort the true cost of health care products in a way that artificially influences consumer activity. Policy should instead empower consumers to make their own decisions, such as choosing among provider and coverage options based on readily accessible quality and price information.

3. Quality and Cost Are Both Important Considerations for Value

As noted at the outset of this paper, the trade-off between quality and cost are fundamental components of considering value. There is little harm in allowing open access to new innovations when consumers can use their own resources. Even when new technology is initially costly, market success can encourage further innovation that decreases the price over time or otherwise makes products more widely available.

In public programs such as Medicare, the government should aim to be a good steward of taxpayer resources, and maintaining programmatic sustainability requires cost-benefit analysis. Yet government programs inherently face political pressure to maintain their popularity by providing generous coverage without denying medical services to needy patients, avoiding the perception of rationing care. There is a fundamental dilemma between freely covering new technology to encourage innovation and restricting access to cut costs, but policymakers should acknowledge these trade-offs directly.

Given that government cannot judge value well but that quality and cost are important factors for public programs to consider nonetheless, it follows that policymakers should incorporate measures of value that are not derived from government decisions — for example, basing Medicare coverage decisions or payment levels off of data from the private market and expanding consumer control over health care decisions.

4. Coverage Criteria Should Be Clear and Consistent

Regardless of how they decide which items and services to cover, public programs such as Medicare will need to manage that process well with concrete criteria. CMS currently retains some formal procedures for notifying the public about its coverage determinations and managing pathways geared toward certain use cases, but it is often unclear to those outside the government when and how it makes those decisions, and they can therefore appear arbitrary. It has generally failed to provide timely and transparent information about its coverage processes or ensure that it is offering prescriptive rubrics for the public that are consistent with its own internal practices, such as its policies for considering cost or when to restrict or terminate coverage due to lack of evidence. The end goal should be to enable innovators to accurately predict the outcome of CMS's decisions without resorting to lobbying and to ensure that CMS's policies achieve their intended aims in terms of obtaining necessary and relevant data on safety and effectiveness.

5. Public Policy Should Not Unnecessarily Increase the Risks of Innovation

Finally, policymakers should have a realistic understanding about *how* innovation improves value in the first place. Assuring a baseline level of quality and cost effectiveness is important even if it imposes costs on innovators but minimizing artificial risk by maintaining predictability, avoiding regulatory burden, lowering barriers to entry, and ensuring appropriate incentives should also be overarching goals. Investing in medical innovation is already risky; government should not unnecessarily add to it.

Policymakers should also understand that innovation is not an all-or-nothing proposition. It is tempting to frame major strides in technology as a single discrete event. In reality, smaller developments incrementally build upon previous innovations to increase effectiveness or availability, which can relieve suffering and improve wellbeing for individuals, thus creating welfare gains for society. For example, periods of exclusivity for brand name drugs allow manufacturers to recoup R&D costs and provide an important incentive to develop new drugs. But once that exclusivity ends, the development of generic drugs often leads to much lower costs that increase access. CMS, FDA, and other federal agencies tend to give special treatment to products that represent dramatic breakthroughs or improvements, which is reasonable. But the importance of "second movers" — such as those who do not develop a new technology but improve upon an existing one — should not be understated.

CONCLUSION

This paper offers background about how government, and Medicare in particular, distorts the health care system so that innovation does not improve value the same way that it does in

other markets. Policymakers should target these statutory and regulatory flaws while keeping in mind five principles: (1) government cannot accurately define value; (2) consumers should be empowered to decide what they most value; (3) quality and cost are both important factors to consider for discerning value; (4) Medicare's coverage criteria should be clear and consistent; and (5) public policy should not unnecessarily increase the risks of innovation by increasing uncertainty, regulatory burden, and barriers to entry both for first movers and for incremental innovators. American health care is unnecessarily costly and wasteful, but fostering a more competitive market rather than relying on the purported wisdom of the federal bureaucracy will improve incentives for private sector innovators to address these shortcomings.