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# The Battle for Medicare

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# THE BATTLE FOR MEDICARE

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ABSTRACT

*America is aging. From 2019 to 2060, the total population of Americans over sixty-five will grow from fifty-four million to ninety-five million. Of all Americans, sixteen percent were aged sixty-five and older in 2019; nearly twenty-two percent are projected to be in this age group by 2040. This shift will put unprecedented pressure on the Medicare program. Its enrollment is already in the midst of an unparalleled boom, growing from forty-eight million in 2010 to eighty-six million by just 2035. As it grows in importance and size, the future of Medicare will be dominated by two competing pressures.*

*First, Medicare has become the primary regulatory vehicle for the federal government and the executive branch in American health care. Its importance as an engine of regulation is highlighted by political gridlock and Medicare's reach. Congressional inaction continues to stymie common-sense health policy development. And, theoretically, one federal dollar—flowing into a hospital's revenues or a provider's pocket—unlocks the extensive regulatory pressure of the Medicare program.*

*Second, the countervailing force is a global deregulatory regime seeking to roll back the administrative state. This regime is most specifically embodied by a newly emboldened Supreme Court, which has signaled hostility to the power and reach of federal agencies. As Medicare becomes more central—and, as it becomes more conspicuous as the primary regulatory vehicle in American health care—it becomes a target of this larger deregulatory project. A recent example of both Medicare's use as a regulatory engine and the hostility to its regulatory power is the Centers for Medicare and Medicaid Services' ("CMS's") recent COVID-19 vaccination mandate for health care workers, and the resulting litigation in federal courts.*

*This essay examines this tension by highlighting the judiciary's treatment of President Biden's vaccination mandate policy while summarizing Medicare's unique position in health care law and policy. These fights between a robust*

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*Medicare program and a global deregulatory effort—perhaps dismissed as academic—will have a real impact on the health and health care of millions of Americans. Regardless of the ultimate resolution of these fights over power and policy, Medicare will serve as the location for turbulent fights over law and power, policy, and values for years to come.*

## I. INTRODUCTION

America is aging.[1] From 2019 to 2060, the total population of Americans over sixty-five will grow from fifty-four million to ninety-five million.[2] Of all Americans, sixteen percent were aged sixty-five and older in 2019; nearly twenty-two percent are projected to be in this age group by 2040.[3] This shift will put unprecedented pressure on the Medicare program.[4] Its enrollment is set to grow to a projected eighty-nine million by 2040,[5] up from forty-seven million in 2010.[6] As it grows in importance and size, the future of Medicare—and, with it, much of the future of American health care—will seemingly be dominated by two competing pressures.

First, Medicare has become the primary regulatory vehicle for the federal government in American health care.[7] Medicare's importance as an engine for regulation is highlighted by political gridlock and Medicare's reach.[8] Congressional inaction continues to stymie common-sense health policy development. And, theoretically, one federal dollar—flowing into a hospital's revenues or a provider's pocket—unlocks the extensive regulatory pressure of the Medicare program.

Second, the countervailing force is a global deregulatory regime, seeking to roll back the administrative state.[9] This regime is most specifically embodied by

1. ADMIN. FOR CMTY. LIVING, U.S. DEP'T OF HEALTH & HUM. SERVS., 2020 PROFILE OF OLDER AMERICANS 4 (May 2021), https://acl.gov/sites/default/files/aging%20and%20Disability%20In%20America/2020Profileolderamericans.final_.pdf; *The US Population Is Aging*, URB. INST., https://www.urban.org/policy-centers/cross-center-initiatives/program-retirement-policy/projects/data-warehouse/what-future-holds/us-population-aging (last visited Jan. 12, 2023).

2. *See supra* note 1, at 5.

3. *Id.*

4. By 2018, Medicare benefit payments totaled $731 billion, which was up from $462 billion in 2008. Juliette Cubanski et al., *The Facts on Medicare Spending and Financing*, KAISER FAM. FOUND. (Aug. 20, 2019), https://www.kff.org/medicare/issue-brief/the-facts-on-medicare-spending-and-financing/ (last visited Nov. 24, 2022). According to projections by the Congressional Budget Office, Medicare's benefit payments should reach $1.3 trillion in 2029. *Id.*

5. *See Projected Change in Medicare Enrollment 2000-2050*, KAISER FAM. FOUND. (July 15, 2013), https://www.kff.org/medicare/slide/projected-change-in-medicare-enrollment-2000-2050/.

6. U.S. DEP'T OF HEALTH & HUM. SERVS., 2010 CMS STATISTICS 1 (June 2010), https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/CMS-Statistics-Reference-Booklet/Downloads/CMS_Stats_2010.pdf.

7. RICK MAYES & ROBERT A. BERENSON, MEDICARE PROSPECTIVE PAYMENT AND THE SHAPING OF U.S. HEALTH CARE 1–2 (2008).

8. Robert Pear & Thomas Kaplan, *Lawmakers Have Bipartisan Health Ideas. Now to Persuade Their Leaders...*, N.Y. TIMES (July 28, 2017), https://www.nytimes.com/2017/07/28/us/politics/health-care-senate-repeal-trump.html; MAYES & BERENSON, *supra* note 7, at 2.

9. *See* Charlie Savage, *E.P.A. Ruling is Milestone in Long Pushback to Regulation of Business*, N.Y. TIMES (June 30, 2022), https://www.nytimes.com/2022/06/30/us/supreme-court-

a newly emboldened Supreme Court,[10] which has signaled hostility to the power and reach of federal agencies.[11] As Medicare becomes more central—and, as it becomes more conspicuous as the primary regulatory vehicle in American health care—it becomes a target of this larger deregulatory project.[12] A recent example of both Medicare's use as a regulatory engine and the hostility to its regulatory power is the Center for Medicare and Medicaid Service's ("CMS's")[13] recent COVID-19 vaccination mandate for health care workers, and the resulting litigation in federal courts.[14]

This essay examines this tension by highlighting the judiciary's treatment of President Biden's vaccination mandate policy while summarizing Medicare's unique position in health care law and policy. These fights between a robust Medicare program and a global deregulatory effort—perhaps dismissed as academic—will have a real impact on the health and health care of millions of Americans.[15] Regardless of the ultimate resolution of these fights over law, power, policy, and values, Medicare will serve as the location for turbulent fights for years to come.[16]

This essay unfolds in three parts. First, in Part II, CMS's so-called "vaccination mandate" will be presented, complete with the judicial history that followed its creation. Part III will outline Medicare's characteristics—both its regulatory primacy, as well as its unique precarity. Finally, in Part IV, concluding thoughts will be presented, including a sketch of what to expect in

epa-administrative-state.html (noting deregulatory efforts in the climate space, and noting the Supreme Court's efforts focused on "curbing the administrative state").

10. *See* Adam Liptak, *A Transformative Term at the Most Conservative Supreme Court in Nearly a Century*, N.Y. TIMES (July 1, 2022), https://www.nytimes.com/2022/07/01/us/supreme-court-term-roe-guns-epa-decisions.html (noting that the 2021-22 term was the most conservative since 1931). *See also* Adam Liptak, *As New Term Starts, Supreme Court is Poised to Resume Rightward Push*, N.Y. TIMES (Oct. 31, 2022), https://www.nytimes.com/2022/10/02/us/conservative-supreme-court-legitimacy.html.

11. *See* David Yaffe-Bellany, *Biden's Agenda Faces a Court System More Hostile to Agency Power*, BLOOMBERG L. (Dec. 15, 2020, 3:00 AM), https://news.bloomberglaw.com/us-law-week/courts-skeptical-of-chevron-may-stymie-bidens-agenda.

12. *See* David Super, *The Court Reads Free-Market Economics into the Constitution (Again)*, WASH. POST (July 5, 2022), https://www.washingtonpost.com/outlook/2022/07/05/epa-supreme-court-environmental-regulations/ (noting a deregulatory result to a case examining the power of the Environmental Protection Agency and noting that the "Roberts Court has now created what is in effect a one-way ratchet favoring deregulation").

13. CTRS. FOR MEDICARE & MEDICAID SERVS., *About CMS*, U.S. DEP'T OF HEALTH & HUM. SERVS., https://www.cms.gov/About-CMS/About-CMS (last visited Jan. 22, 2023).

14. Biden v. Missouri, No. 21A240, slip op. at 3 (U.S. Jan. 13, 2022).

15. ANDREW TWINAMATSIKO & KATIE KEITH, SLOUCHING TOWARDS DEREGULATION: THE THREAT TO HEALTH POLICY 1–2 (Apr. 2022), https://oneill.law.georgetown.edu/wp-content/uploads/2022/04/ONL_Derugulation_Report_P4.pdf.

16. Jonathan Oberlander, *The Politics of Medicare Reform*, 60 WASH. & LEE L. REV. 1095, 1095, 1102 (2003).

the future. Although the specific contours of future regulatory battles remain murky, key themes in the battle—highlighted by the CMS vaccination mandate—will nonetheless endure.

## II. MEDICARE'S COVID-19 VACCINATION MANDATE

The central focus of this paper—the Biden administration's rule that health care workers employed by facilities that receive Medicare dollars get a COVID-19 vaccination, and the resulting legal review—is provided immediately below.[17] In order to analyze the key legal decisions, the summary is broken down into three parts: (1) the CMS vaccination mandate is presented, (2) the district courts' analyses are summarized, and (3) the United States Supreme Court's decision—issued in January of 2022—is examined.

### *A. The Centers for Medicare and Medicaid Services Mandate*

On November 4, 2021, the Biden administration announced a COVID-19[18] vaccination mandate for "eligible staff at health care facilities that participate in the Medicare and Medicaid programs."[19] The administration promulgated the rule after concluding that "its earlier efforts to simply encourage vaccination [had] been insufficient to protect health and safety."[20] The rule also noted the "inconsistent patchwork of requirements and laws that is only effective at local levels" and that had "not successfully raised staff vaccination rates nationwide."[21] As an example of low uptake rate, the national vaccination rate for nursing home staff was seventy-six percent as of November 2021.[22]

According to CMS, the new rule was to "create a consistent standard within Medicare and Medicaid while giving patients assurance of the vaccination status of those delivering care."[23] While Medicare had never before mandated a

17. *Biden-Harris Administration Issues Emergency Regulation Requiring COVID-19 Vaccination for Health Care Workers*, CTRS. FOR MEDICARE & MEDICAID SERVS. (Nov. 4, 2021), https://www.cms.gov/newsroom/press-releases/biden-harris-administration-issues-emergency-regulation-requiring-covid-19-vaccination-health-care; Biden v. Missouri, slip op. at 3.

18. *See Coronavirus in the U.S.: Latest Map and Case Count*, N.Y. TIMES, https://www.nytimes.com/interactive/2021/us/covid-cases.html (last updated Feb. 9, 2023) (documenting cases, vaccinations, and deaths throughout the COVID-19 outbreak since February of 2020).

19. CTRS. FOR MEDICARE & MEDICAID SERVS., *supra* note 17.

20. MaryBeth Musumeci, *Explaining the New COVID-19 Vaccination Requirement for Health Care Provider Staff*, KAISER FAM. FOUND. (Dec. 15, 2021), https://www.kff.org/coronavirus-covid-19/issue-brief/explaining-the-new-covid-19-vaccination-requirement-for-health-care-provider-staff/.

21. Medicare and Medicaid Programs; Omnibus COVID-19 Health Care Staff Vaccination, 86 Fed. Reg. 61555, 61566 (Nov. 5, 2021).

22. Musumeci, *supra* note 20.

23. CTRS. FOR MEDICARE & MEDICAID SERVS., *supra* note 17.

specific vaccination applicable to health care staff, the regulation fell within CMS's regulatory authority to protect the health and safety of its beneficiaries.[24]

CMS justified the new rule as protecting patients. CMS noted that, "[i]n light of our responsibility to protect the health and safety of individuals providing and receiving care and services from the Medicare and Medicaid certified providers and suppliers, and CMS's broad authority to establish health and safety regulations, we are compelled to require staff vaccinations for COVID-19 in these settings."[25] Categorized as patient protection, this rule did not reflect any new kind of CMS regulatory authority.[26] Further, it was politically supported—more than fifty percent of Americans polled supported a government mandate for health care workers.[27]

In short, Medicare and Medicaid—as public payers for health care services—sought to impose quality of care for its beneficiaries by requiring that health care providers and staff get vaccinated against COVID-19.[28] The rule was placed within Medicare and Medicaid's "Conditions of Participation," ("CoPs"), which are, according to CMS, "foundational health and safety standards established by CMS to protect individuals receiving health care services from Medicare and Medicaid-certified facilities."[29] Like in other contexts, those hospitals and providers participating in Medicare and Medicaid were subject to the new vaccination-mandate CoP, but independent physicians and clinicians were not.[30] Even if the federal government wanted to force all providers nationwide to be vaccinated, CMS lacked administrative authority to establish a universal rule.[31]

Further, according to CMS, just like other CoPs, the Agency announced it would ensure compliance with these requirements through established survey and enforcement processes.[32] If a provider or supplier did not meet the requirements, it was to be cited by a surveyor as being non-compliant, and have an opportunity at a later time to become compliant before additional actions

24. Biden v. Missouri, No. 21A240, slip op. at 7–8 (U.S. Jan. 13, 2022).

25. Medicare and Medicaid Programs; Omnibus COVID-19 Health Care Staff Vaccination, 86 Fed. Reg. at 61560.

26. *Id.*

27. *See* Kathy Frankovic, *Americans Tend to Support Biden's Vaccine Mandates for Health-Care Workers and Large Companies,* YOUGOV (Jan. 7, 2022), https://today.yougov.com/topics/politics/articles-reports/2022/01/07/americans-support-bidens-vaccine-mandates-poll

28. Medicare and Medicaid Programs; Omnibus COVID-19 Health Care Staff Vaccination, 86 Fed. Reg. at 61560.

29. *External FAQ: CMS Omnibus COVID-19 Health Care Staff Vaccination Interim Final Rule*, CTRS. FOR MEDICARE & MEDICAID SERVS. (Jan. 20, 2022), https://www.cms.gov/files/document/cms-omnibus-covid-19-health-care-staff-vaccination-requirements-2021.pdf

30. *Id.*

31. *Id.*

32. *Id.*

occur.[33] CMS's goal was to bring health care providers into compliance.[34] CMS has stated that, "the Agency will not hesitate to use its full enforcement authority to protect the health and safety of patients."[35]

Facilities that failed to meet the new regulatory requirements were subject to civil monetary penalties ("CMPs"),[36] denial of payment, and termination from Medicare and Medicaid. However, it seems clear that CMS's primary goal was to ensure compliance with the mandate.[37]

### *B. The District Court Cases*

The unchallenged rule was short-lived. On November 10, 2021, ten states sued in federal court seeking injunctive relief.[38] On November 29, 2021, the Eastern District of Missouri—in an opinion written by Judge Matthew T. Schelp—granted a preliminary injunction against the enforcement of the vaccine mandate,[39] finding that Congress never authorized the action that CMS took in issuing the mandate.[40]

Given the vast economic and political significance of the mandate, the court found that, for it to uphold the mandate, CMS must have been given clear authorization from Congress.[41] Additionally, the district court found that Congress must use "exceedingly clear language" where "it wishes to significantly alter the balance between federal and state power."[42] Here, the court concluded that the rule altered that balance "because it requires vaccination, which CMS has never attempted to do, for millions of individuals who would otherwise be outside the reach of the federal government."[43] Further, the court noted that "[t]his concern is 'heightened' since CMS's administrative interpretation alters the federal-state framework by permitting federal encroachment upon a traditional state power."[44]

33. *Id.*

34. CTRS. FOR MEDICARE & MEDICAID SERVS., *supra* note 29.

35. CTRS. FOR MEDICARE & MEDICAID SERVS., *supra* note 17.

36. A host of Civil Monetary Penalties (CMPs) are available to government agencies. These include a number of health care-related CMPs available to the Office of Inspector General within the Department of Health and Human Services (HHS). *See Civil Monetary Penalty Authorities*, DEP'T OF HEALTH & HUM. SERVS., https://oig.hhs.gov/fraud/enforcement/civil-monetary-penalty-authorities/ (last visited Feb. 3, 2023).

37. *See* CTRS. FOR MEDICARE & MEDICAID SERVS., *supra* note 29.

38. *See* Missouri v. Biden, 571 F. Supp. 3d 1079, 1085 (E.D. Mo. 2021).

39. *Id.*

40. *Id.* at 1086.

41. *Id.* at 1089.

42. *Id.* at 1088 (citing Ala. Ass'n of Realtors v. Dep't of Health & Hum. Servs., 141 S. Ct. 2485, 2486 (2021).

43. Missouri v. Biden, 571 F. Supp. 3d at 1088.

44. *Id.*

The court struck at the heart of CMS's regulatory authority by arguing that *states*, not CMS, have typically had the responsibility and the authority for devising policies that compel vaccination.[45] The court continued:

> Truly, the impact of this mandate reaches far beyond COVID. CMS seeks to overtake an area of traditional state authority by imposing an unprecedented demand to federally dictate the private medical decisions of millions of Americans. Such action challenges traditional notions of federalism, as discussed above. "The independent power of the States [ ] serves as a check on the power of the Federal Government: by denying any one government complete jurisdiction over all the concerns of public life, federalism protects the liberty of the individual from arbitrary power." . . . This is especially true, since "a healthy balance of power between the States and the Federal Government will reduce the risk of tyranny and abuse from either front."[46]

The court seemed skeptical of whether Congress could have mandated such a policy, but found that "even if Congress's statutory language was susceptible to CMS's exceedingly broad reading—which it is most likely not—Congress did not clearly authorize CMS to enact the [sic] this politically and economically vast, federalism-altering, and boundary-pushing mandate, which Supreme Court precedent requires."[47] The court enjoined the mandate in Alaska, Arkansas, Iowa, Kansas, Missouri, Nebraska, New Hampshire, North Dakota, South Dakota, and Wyoming.[48]

The next day, on November 30, 2021, the district court in the Western District of Louisiana also enjoined the mandate.[49] Fourteen states—Alabama, Arizona, Georgia, Idaho, Indiana, Kentucky, Louisiana, Mississippi, Montana, Ohio, Oklahoma, South Carolina, Utah, and West Virginia—joined in this litigation.[50] Similar to the Eastern District of Missouri, and in a sweeping decision, Judge Terry A. Doughty found that (1) the states challenging the mandate had standing, (2) CMS lacked the authority to issue such a mandate, and (3) the rule was arbitrary and capricious.[51] On the point as to whether CMS had the authority to issue such a rule, the court wrote:

> Only Congress as the Legislative branch, has the authority to make laws.... There is no question that mandating a vaccine to 10.3 million healthcare workers is something that should be done by Congress, not a government agency. It is not clear that even an Act of Congress mandating a vaccine would be

45. *Id.*

46. *Id.* at 1088–89 (citations omitted).

47. *Id.* at 1089.

48. Missouri v. Biden, 571 F. Supp. 3d at 1104.

49. *See* Louisiana v. Becerra, 571 F. Supp. 3d 516, 526 (W.D. La. 2021).

50. *See* Greg Hilburn, *Louisiana at Forefront of COVID Vaccine Mandate Debate at Supreme Court*, LAFAYETTE DAILY ADVERTISER (Jan. 4, 2022), https://www.theadvertiser.com/story/news/2022/01/04/louisiana-forefront-covid-vaccine-mandate-debate-supreme-court/9076489002/.

51. *See Becerra*, 571 F. Supp. 3d at 529, 537, 540.

> constitutional. Certainly, CMS does not have this authority by a general authorization statue [sic].[52]

The court implied that the "major questions doctrine"[53] was violated by the mandate, noting that CMS did not address it in its argument, and that, because the mandate represented a "decision of vast economic and political significance,"[54] it needed direct empowerment from Congress.

Finally, the Western District of Louisiana found that the CMS mandate violated particular provisions of the Social Security Act.[55] The court concluded the rule was arbitrary and capricious, noting that the mandate did not "yet require boosters to the COVID-19 vaccines."[56] Judge Doughty asked, in the opinion, "[i]f boosters are needed six months after being 'fully vaccinated,' then how good are the COVID-19 vaccines, and why is it necessary to mandate them?"[57] He continued,

> Although CMS spent pages and pages attempting to explain the need for mandatory COVID-19 vaccines, when infection and hospitalizations rates are dropping, millions of people have already been infected, developing some form of natural immunity, and when people who have been fully vaccinated still become infected, mandatory vaccines as the only method of prevention make no sense.[58]

### *C. The Supreme Court Case*

Although the Fifth Circuit[59] did issue an opinion on appeal, it was the U.S. Supreme Court that "fast tracked" the litigation, and heard oral arguments on January 7, 2022.[60] On January 13, 2022, the U.S. Supreme Court upheld the

52. *Id.* at 535, 537.

53. The major questions doctrine was a focus of the Supreme Court's jurisprudence in the 2021-22 term, and, in particular, was used to severely limit the authority of the Environmental Protection Agency (EPA) to act under the Clean Air Act. *See* Carrie Jenks, Hannah Oakes, and Sara Dewey, *Supreme Court Embraces the Major Questions Doctrine As Limiting but Leaving the Door Open for Power Sector GHG Regulations*, HARV.ENV'T & ENERGY L. PROGRAM (July 1, 2022), https://eelp.law.harvard.edu/2022/07/supreme-court-embraces-the-major-questions-doctrine-as-limiting-but-leaving-the-door-open-for-power-sector-ghg-regulations/ (discussing the major questions doctrine in context).

54. *See Becerra*, 571 F. Supp. 3d at 536–37.

55. *Id.* at 537–38.

56. *Id.* at 539–40.

57. *Id.* at 539

58. *Id.* at 539–40.

59. Louisiana v. Becerra, 20 F.4th 260, 262 (5th Cir. 2021).

60. *See* Amy Howe, *Justices Will Hear Arguments on Jan. 7 in Challenges to Biden Vaccine Policies*, SCOTUSBLOG (Dec. 22, 2021, 8:55 PM), https://www.scotusblog.com/2021/12/justices-will-hear-arguments-on-jan-7-in-challenges-to-biden-vaccine-policies/.

Biden administration's Medicare and Medicaid vaccination mandate by a vote of 5-4 in *Missouri v. Biden*.[61]

In the opinion, the majority of justices found that the Department of Health and Human Services ("HHS") Secretary, Xavier Becerra, had the legal authority to enforce a vaccination mandate against employees of hospitals that accept Medicare funding.[62] Crediting the Secretary's determination that the "vaccination of health care workers against COVID-19 was 'necessary for the health and safety of individuals to whom care and services are furnished,'" the Court agreed that unvaccinated staff members "pose a serious threat to the health and safety of patients," the virus "can spread rapidly among healthcare workers and from them to patients, and that such spread is more likely when healthcare workers are unvaccinated."[63] The Court also found that the Secretary's determination to issue the rule as an interim final rule, and not "through the typical notice-and-comment procedures" was based on the belief that any delay in rule-making "would endanger patient health and safety given the spread of the Delta variant and the upcoming winter season."[64]

The majority found that the Secretary's rule had, indeed, gone "further than what the Secretary has done in the past to implement infection control," but "there can be no doubt that addressing infection problems in Medicare and Medicaid facilities is what he does."[65] The majority focused on the grant of power that the Agency has.[66] The majority concluded:

> The challenges posed by a global pandemic do not allow a federal agency to exercise power that Congress has not conferred upon it. At the same time, such unprecedented circumstances provide no grounds for limiting the exercise of authorities the agency has long been recognized to have. Because the latter principle governs in these cases, the applications for a stay presented to Justice Alito and Justice Kavanaugh and by them referred to the Court are granted.[67]

Four justices found that CMS lacked the power to require vaccination, and that CMS did not follow appropriate administrative law procedures.[68] The first dissent, authored by Justice Thomas and joined by Justices Alito, Gorsuch, and Barrett, noted that the vaccination rule was only "tangential[ly]" related to the administration of Medicare and Medicaid.[69] Further, the Thomas dissent noted

61. Biden v. Missouri, No. 21A240, slip op. at 10 (U.S. Jan. 13, 2022).

62. *Id.* at 8.

63. *Id.* at 3.

64. *Id.* at 4.

65. *Id.* at 7.

66. Biden v. Missouri, slip op. at 9.

67. *Id.* at 9–10.

68. Biden v. Missouri, No. 21A240, Thomas, J., dissenting, slip op. at 1, 8 (U.S. Jan. 13, 2022); Biden v. Missouri, No. 21A240, Alito, J., dissenting, slip op. at 1, 4–5 (U.S. Jan. 13, 2022).

69. Biden v. Missouri, No. 21A240, Thomas, J., dissenting, slip op. at 2–3 (U.S. Jan. 13, 2022).

that "[h]ad Congress wanted to grant CMS power to impose a vaccine mandate across all facility types, it would have done what it has done elsewhere—specifically authorize one."[70] Of course, Congress—when creating the Medicare and Medicaid programs—could have never foreseen what kind of threat the COVID-19 pandemic might bring fifty-five years in the future.

Justice Alito, who also authored a dissent joined by the same dissenting justices, lamented that, today, "most federal law is not made by Congress," and "comes in the form of rules issued by unelected administrators."[71] He also noted that "I do not think the Federal government is likely to be able to show that Congress has authorized the unprecedented step of compelling over 10,000,000 healthcare workers to be vaccinated on pain of being fired."[72] Justice Alito then took issue with the agency's failure to follow typical notice and comment procedures.[73] After the result, CMS Administrator Chiquita Brooks-LaSure praised the decision, stating that "[g]iving patients assurance on the safety of their care is a critical responsibility of CMS and a key to combatting the pandemic."[74]

## III. MEDICARE, FROM A REGULATORY PERSPECTIVE

CMS, and particularly Medicare, is no stranger to regulating health care in the United States—indeed, health law and administrative law are tightly wound up with one another,[75] and Medicare is tightly wound up with the regulatory infrastructure of American health care.[76] As other scholars have argued, Medicare is a unique program whose structure presents particular challenges.[77] These challenges then lead to a regulatory structure that at times can seem both voluntary and draconian, both legally-required and free market. In a general sense, Medicare's architecture has hamstrung its ability to be run more efficiently.[78] More specifically, Medicare is hammered in multiple directions.

70. *Id.* at 4.

71. Biden v. Missouri, No. 21A240, Alito, J., dissenting, slip op. at 2 (U.S. Jan. 13, 2022)..

72. *Id.* at 1.

73. *Id.* at 2.

74. *See Statement by CMS Administrator Chiquita Brooks-LaSure On the U.S. Supreme Court's Decision on Vaccine Requirements*, CTRS. FOR MEDICARE & MEDICAID SERVS. (Jan. 13, 2022), https://www.cms.gov/newsroom/press-releases/statement-cms-administrator-chiquita-brooks-lasure-us-supreme-courts-decision-vaccine-requirements.

75. *See* Timothy Stoltzfus Jost, *Health Law and Administrative Law: A Marriage Most Convenient*, 49 ST. LOUIS U. L.J. 1, 33 (2004) ("Administrative law, therefore, will continue to be inextricably entwined with health law.").

76. *Id.*

77. Marilyn Moon, *Medicare Matters: Building on a Record of Accomplishments*, HEALTH CARE FIN. REV., Fall 2000, at 9, 14, 16.

78. *Id.* at 14, 16–17.

This is due to a number of structural features of the program, as well as the federal government's chosen answers to policy challenges.[79]

Nonetheless, as an initial matter, Medicare has a number of structural quality-enhancing mandates called conditions of participation.[80] These include, among others, a requirement that providers and hospitals obtain informed consent,[81] implement effective infection control protocols,[82] maintain hospital records for five years,[83] secure sanitary environments,[84] and require psychiatric hospitals to have adequate numbers of qualified providers.[85] These CoPs are fairly broad and give Medicare facilities "detailed standards governing the practice of individual scientific disciplines."[86] In other words, they set the standards for what the Medicare program expects of its participating hospitals and providers.

There are a couple of unique characteristics that are worth highlighting. First, Medicare operates as a constituent payer—part of the landscape of American health care payers—and not dissimilar from other private payers.[87] In this way, the government program arguably constrains the power available to it. Second, Medicare operates as a regulatory channel for the federal government—albeit one that is built on a voluntary structure.[88] Third, Medicare—and its federal regulatory entity, CMS—is the primary vehicle for regulatory

79. *Id.* at 14. *See generally* ELIZABETH DOCTEUR ET AL., NAT'L ACAD. OF SOC. INS., EXAMINING APPROACHES TO EXPAND MEDICARE ELIGIBILITY: KEY DESIGN OPTIONS AND IMPLICATIONS 8, 15 (Mar. 2020).

80. *See* Nicole Huberfeld, *Be Not Afraid of Change: Time to Eliminate the Corporate Practice of Medicine Doctrine*, 14 HEALTH MATRIX 243, 279–80 (2004) ("To participate in Medicare, all health care providers must meet federal standards for their specific type of health care entity, called 'conditions of participation.'").

81. *See generally* Isaac D. Buck, *Overtreatment and Informed Consent*, 43 FLA. ST. U. L. REV. 901 (2017).

82. 42 C.F.R. § 482.42 (2022).

83. *See* Stacey A. Tovino, *The HIPAA Privacy Rule and the EU GDPR: Illustrative Comparison,* 47 SETON HALL L. REV. 973, 991 (2017) ("For example, the federal Medicare Conditions of Participation require Medicare-participating hospitals to maintain hospital medical record for five years.").

84. Stacey A. Tovino, *The Grapes of Wrath: On the Health of Immigration Detainees,* 57 B.C. L. REV. 167, 213 (2016).

85. *Id.* at 212.

86. Joan H. Krause, *"Promises to Keep": Health Care Providers and the Civil False Claims Act*, 23 CARDOZO L. REV. 1363, 1399 (2002).

87. Anne M. Lockner, *Insight: The Healthcare Industry's Shift from Fee-for-Service to Value-Based Reimbursement*, BLOOMBERG L. (Sept. 26, 2018, 8:30 AM), https://news.bloomberglaw.com/health-law-and-business/insight-the-healthcare-industrys-shift-from-fee-for-service-to-value-based-reimbursement.

88. *Quality, Safety & Oversight – Certification & Compliance*, CTRS. FOR MEDICARE & MEDICAID SERVS. (July 13, 2022, 7:53 PM), https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/CertificationandComplianc.

enforcement through the use of financial enticements.[89] In other words, in an effort to solve negative externalities and other regulatory challenges, the federal government has elected to rely on voluntary reimbursement-based regulation—again, using the Medicare program as the primary vehicle in that project. The result is a fragmented and "free-market" regulatory structure for American health care.[90]

### *A. A Payer Among Payers*

At its core and since its inception, Medicare has been a payer of health care services for America's elderly.[91] As of 2020, the program provides health insurance for 61.2 million Americans,[92] and pays for their health care primarily through taxpayer contributions.[93] This program has become indispensable for this population. In many ways, Medicare does not operate like a state-owned, taxpayer-funded, public program; it receives no special treatment by health care providers and entities.[94]

Indeed, as a functional actor, Medicare operates in a way that is not dissimilar from private insurance payers.[95] Mirroring the way providers and entities get reimbursed by a private payer, providers and entities qualify for the Medicare program, treat Medicare's beneficiaries, and then bill the program for services.[96] Medicare determines which services to pay for through both local and national coverage determinations ("LCDs" and "NCDs", respectively),[97] and pays for those services.[98] In creating Medicare, policymakers elected to create a program that would enable Medicare beneficiaries to access a largely-private system. This system was to be no different, in effect, from private-paying

89. *Id.*; *Medicare: Implementation of Financial Incentive Programs under Federal Fraud and Abuse Laws*, U.S. GOV'T ACCOUNTABILITY OFF. (Mar. 30, 2012), https://www.gao.gov/products/gao-12-355.

90. Gerard F. Anderson et al., *It's Still the Prices, Stupid: Why the U.S. Spends SO Much on Health Care, and A Tribute to Uwe Reinhardt*, 38 HEALTH AFFS. 87, 92 (2019); Robert I. Field, *Government as the Crucible for Free Market Health Care: Regulation, Reimbursement, and Reform*, 159 U. PA. L. REV. 1669, 1670, 1694 (2011).

91. Field, *supra* note 90, at 1687–88; *An Overview of Medicare,* KAISER FAM. FOUND. (Feb. 13, 2019), https://www.kff.org/medicare/issue-brief/an-overview-of-medicare/.

92. *Total Number of Medicare Beneficiaries*, KAISER FAM. FOUND., https://www.kff.org/medicare/state-indicator/total-medicare-beneficiaries/ (last visited Feb. 3, 2023).

93. *See* KAISER FAM. FOUND., *supra* note 91 (noting that 41 percent of Medicare was financed by general revenues, 37 percent by payroll tax contributions, and 14 percent by beneficiary premiums, in 2017).

94. *Id.*

95. Lockner, *supra* note 87.

96. *Id.*

97. *See* Kirk Dobbins and Kay Scanlan, *Medicare's Revised Clinical Trial Policy and Clinical Trial-Related Provisions of FDAAA: What Is A Sponsor to Do?*, 62 FOOD & DRUG L.J. 695, 703 (2007) ("In the absence of NCDs, LCDs establish local Medicare coverage and payment policy.").

98. *Id.*

patients, as opposed to building a wholly separate public system like those seen in other countries.[99] However, Medicare is not the same as other insurance companies.

First, Medicare is a regulatory trend-setter within American health care.[100] One example of this phenomenon is with its focus on accountable care organizations ("ACOs").[101] Indeed, "[a]lthough early adopters of the ACO model commonly operated under the CMS Medicare Shared Shavings Program ("MSSP") or the Pioneer ACO Program, recent market entrants have included ACOs in the private market."[102] In fact, in many prescriptive policy programs, Medicare invests public money to try new programs and pilots, and if they are profitable and successful, private industry is interested in them as well.[103] In this way, Medicare serves as a conduit for good policy ideas in an effort to get them to take hold in the private marketplace.[104]

What makes Medicare even more fundamentally different from private insurance payers is its directive to cover a population that is most likely to need and utilize health care services—Americans older than sixty-five.[105] Medicare

99. Indeed, this is similar to Canada—"[i]n Canada, the government finances health insurance, and the private sector delivers a lot of the care." Aaron E. Carroll and Austin Frakt, *The Best Health Care System in the World: Which One Would You Pick?*, N.Y. Times (Sept. 18, 2017), https://www.nytimes.com/interactive/2017/09/18/upshot/best-health-care-system-country-brack et.html. In Britain, however, "[t]he government not only finances care, but also provides it through the National Health Service." *Id.* Canada's system is more like Medicare, and the British system is more like the Veterans Health Administration in the United States. *Id. See also* Lauren Frayer, *U.K. Hospitals Are Overburdened, But the British Love Their Universal Health Care*, NPR (Mar. 7, 2018, 8:17 AM), https://www.npr.org/sections/parallels/2018/03/07/591128836/u-k-hospitals-are-overburdened-but-the-british-love-their-universal-health-care (noting the U.K.'s public hospitals); Roosa Tikkanen et al., *International Health Care System Profiles: England,* COMMONWEALTH FUND (June 5, 2020), https://www.commonwealthfund.org/international-health-policy-center /countries/england (noting 64 public hospitals in the U.K. are "directly accountable to the Department of Health" and 142 are "foundation trusts regulated by NHS Improvement").

100. Ateev Mehrotra & Vivian Ho, *A Simple Solution to Ending 'Surprise' Medical Bills: Bundled Payments*, STAT (Nov. 2, 2018), https://www.statnews.com/2018/11/02/solution-ending-surprise-medical-bills-bundled-payments/.

101. *See Accountable Care Organizations (ACOs): General Information*, CTRS. FOR MEDICARE & MEDICAID SERVS., https://innovation.cms.gov/innovation-models/aco (last updated Oct. 12, 2022).

102. Ann Scheck McAlearney, Brian Hilligoss, and Paula H. Song, *Private Sector Accountable Care Organization Development: A Qualitative Study*, AM. J. MANAGED CARE, Mar. 2017., at 151, 151.

103. *See About the CMS Innovation Center*, CTRS. FOR MEDICARE & MEDICAID SERVS., https://innovation.cms.gov/about (last updated Dec. 12, 2022).

104. Mehrotra & Ho, *supra* note 100.

105. Even though Medicare provides coverage for those over 65, Medicare also covers individuals with disabilities under 65. *See Medicare Coverage for People with Disabilities*, CTR. FOR MEDICARE ADVOC., https://medicareadvocacy.org/medicare-info/medicare-coverage-for-people-with-disabilities/ (last visited Jan. 15, 2023).

covers the patients that private insurance companies try to avoid.[106] In this way, Medicare serves as a subsidy for private insurers, as it covers individuals that private companies would wish to deny. As such, Medicare operates on a day-to-day basis as would a private insurance company, but its mission and focus make it clear it is fundamentally different.[107]

Additionally, not only is it the case that Medicare covers individuals for whom there is often no profit motive to do so, it quietly removes an additional burden off the private insurance industry. Specifically, because Medicare is covering the costs associated with maladies that emerge at an advanced age, the existence of Medicare creates a disincentive for private insurance companies to address many expensive long-term and chronic risks.[108] Although some expensive, serious health care risks may materialize in early life, most chronic conditions are correlated with age, making Medicare the insurance company for the population of Americans most likely to have chronic conditions.[109] This removes a major burden from private insurance companies.[110] Additionally, due to Medicare's substantial reimbursement formulas, hospitals—historically—have been happy to treat Medicare patients.[111]

Medicare's character makes it as much a safety net as an insurance company. As health *risks* are certain to materialize into a health care *need* over time, private insurance companies are not interested in paying—and Medicare, by virtue of covering nearly all Americans of retirement age, does.[112] In this way, the program provides a hidden subsidy to private insurance companies. Private insurance companies are in better financial shape in a world in which Medicare exists.[113]

106. MICHELLE GRISAT, MEDICARE FOR ALL VS. ALL THE HEALTHCARE THAT EACH CAN AFFORD, SANDERS INST. 4 (2017).

107. *See CMS' Program History*, CTRS. FOR MEDICARE & MEDICAID SERVS., https://www.cms.gov/About-CMS/Agency-Information/History (last modified Dec. 1, 2021).

108. GRISAT, *supra* note 106, at 5.

109. *See* Peter Boersma et al., *Prevalence of Multiple Chronic Conditions Among US Adults, 2018*, CTRS. FOR DISEASE CONTROL & PREVENTION, Sept. 2020, at 1, 2 (noting that prevalence of chronic conditions was highest among adults aged 65 or older, among other demographics, and that the prevalence of multiple chronic conditions ranged from 58.5 to 76.9 percent of Americans aged 65 and older, among different insurance coverages, compared to those aged 18-64, which says a range of 11.6 percent to 27.6 percent).

110. GRISAT, *supra* note 106, at 3, 4.

111. *See* Robert Martensen, *How Medicare and Hospitals Have Shaped American Health Care*, J. ETHICS, Nov. 2011, at 808, 808 ("Nonetheless, for hospitals, especially urban ones, Medicare and Medicaid caused a sea change. What had been for centuries their most problematic service group—the elderly indigent—in a trice had become, now that their care was monetized, desirable.").

112. *Id.*; GRISAT, *supra* note 106, at 3.

113. *Steffie Woolhandler, 'Medicare Buy-In' Called a Subsidy to Private Insurers*, PNHP, https://pnhp.org/news/medicare-buy-in-called-a-subsidy-to-private-insurers/ (last visited Jan. 19, 2023).

### B. *The Trickiness of Voluntariness*

Participation in Medicare—for providers and entities—is voluntary.[114] There is no Medicare mandate. If a provider does not wish to comply with Medicare's CoPs, no provider has to do so.[115]

Even though it is still rare to find a provider or entity that does not accept Medicare and does not treat Medicare's beneficiaries, it remains a completely voluntary program.[116] As a result, in a hypothetical world in which a CoP becomes too onerous or draconian, providers and entities could drop out of the Medicare program without legal penalty.[117]

Medicare reimbursement regulation carries with it a major compliance risk. Federal statutes—including the False Claims Act,[118] the Anti-Kickback Statute,[119] and the Stark Law[120]—threaten penalties for providers who violate reimbursement rules under the Medicare program.[121] For providers and entities who violate these provisions, Medicare applies an exclusionary penalty as well, which bans offending parties from participating in the program for a set period of time.[122] This has been referred to as the "death penalty" for health care providers and entities.[123]

Overall, just like private insurance companies, Medicare's voluntary nature means that it has to maintain a reimbursement, regulatory, and oversight structure that ensures continued participation by providers.[124] This is nothing

114. *Does your provider accept Medicare as full payment?* MEDICARE.GOV, https://www.medicare.gov/basics/costs/medicare-costs/provider-accept-Medicare (last visited Jan. 19, 2023).

115. *Id.*

116. In 2015, 93 percent of non-pediatric primary care doctors accept Medicare. *See* Cristina Boccuti et al., *Primary Care Physicians Accepting Medicare: A Snapshot*, KAISER FAM. FOUND. (Oct. 30, 2015), https://www.kff.org/medicare/issue-brief/primary-care-physicians-accepting-medicare-a-snapshot/. In 2022, a study found that most physicians accept new Medicare patients at roughly the same rate that they accept new patients with private insurance. *See* Nancy Ochieng et al., *Most Office-Based Physicians Accept New Patients, Including Patients with Medicare and Private Insurance*, KAISER FAM. FOUND. (May 12, 2022), https://www.kff.org/medicare/issue-brief/most-office-based-physicians-accept-new-patients-including-patients-with-medicare-and-private-insurance/.

117. This remains a rare occurrence. *See* Ochieng, *supra* note 116 (finding that 1.0 percent of physicians have formally opted-out of Medicare, but that 7.5 percent of psychiatrists have done so). Further, nearly four percent of physicians who specialize in plastic and reconstructive surgery and nearly three percent of neurologists have opted out of Medicare. *Id.*

118. *See* 31 U.S.C. § 3729.

119. *See* 42 U.S.C. § 1320a–7b.

120. *See* 42 U.S.C. § 1395nn.

121. Isaac D. Buck, *Caring Too Much: Misapplying the False Claims Act to Target Overtreatment*, 74 OHIO ST. L.J. 463, 506 n.287 (2013).

122. *Id.*

123. *Id.* at 506–07.

124. Karyn Schwartz et al., *Limiting Private Insurance Reimbursement to Medicare Rates Would Reduce Health Spending by About $350 Billion in 2021*, KAISER FAM. FOUND. (Mar. 1,

new for an insurance company to be attuned to—they have to adopt coverage policies to ensure that providers will wish to accept and treat their beneficiaries.[125] If an insurance company pays too little in reimbursement,[126] has too much oversight, or requires narrower networks,[127] providers can flee. In this way, the insurance company is selling itself and its beneficiaries to the providers as much as the providers and entities are selling themselves to the insurance companies.[128] Medicare must do this as well.

This typical application in the private market feels different when applied to the seminal public program. Unlike public insurance financing in other countries where the coverage mechanism is universal, or nearly so,[129] Medicare in the United States has to carefully strike the right balance. Specifically, Medicare must apply cost pressure to providers so as to keep the program afloat, but *not too much* in the event they may recoil and exit the program altogether.[130] In other words, Medicare tries to operate as a consumer, but—in the end—cannot say "no."

One need look no further than the other public insurance program of Medicaid for an example of a program that has driven providers away from participation due, at least partly, to its often exceptionally low reimbursement rates.[131] Medicaid's low reimbursement rates have led to allegations that its

2021), https://www.kff.org/medicare/issue-brief/limiting-private-insurance-reimbursement-to-medicare-rates-would-reduce-health-spending-by-about-350-billion-in-2021/.

125. *Id.*

126. *See* Phil Galewitz, *Needy Patients "Caught in the Middle" as Insurance Titan Drops Doctors*, FAM. FOUND. (Feb. 25, 2020), https://khn.org/news/needy-patients-caught-in-the-middle-as-insurance-titan-drops-doctors/ ("Across the nation, business and contractual disputes are separating patients from longtime doctors. This often occurs when doctors don't want to accept the rates insurers are willing to pay.").

127. *Id.*

128. Eric Lopez et al., *How Much More Than Medicare Do Private Insurers Pay? A Review of the Literature*, KAISER FAM. FOUND. (Apr. 15, 2020), https://www.kff.org/medicare/issue-brief/how-much-more-than-medicare-do-private-insurers-pay-a-review-of-the-literature/.

129. For example, in Britain, the National Health Service covers all residents through general taxation. *See* Tikkanen et al., *supra* note 99.Nonetheless, 10.5 percent of the U.K. population carried private voluntary health insurance in 2015. *Id.*

130. An area where this is particularly sensitive is in hospital reimbursement. *See Private Health Plans Pay Hospitals 241% of What Medicare Would Pay*, RAND CORP. (May 9, 2019), https://www.rand.org/news/press/2019/05/09.html (noting widely disparate reimbursement rates, with private insurance paying hospitals 241 percent of what Medicare pays for the same procedures). Further, as Medicare's reimbursement rates have remained flat, the program often pays less than providers and entities expend to treat beneficiaries. *See* Annaliese Johnson, *Medicare Rates as a Benchmark: Too Much, Too Little or Just Right?*, ALTARUM HEALTHCARE VALUE LAB (Aug. 2021), https://www.healthcarevaluehub.org/application/files/2916/2982/7951/Altarum-Hub_RB_44_-_Health_Equity.pdf.

131. In February 2007, 12-year-old Deamonte Driver died of a toothache in Maryland, a tragic case study for how poor access to care was for Medicaid beneficiaries in the state. *See* Meghan Gallagher, *Death From a Toothache: The Story of Deamonte Driver and Where We Stand Today*

funding mechanism constitutes discrimination.[132] Recent Supreme Court jurisprudence has held that Medicaid providers cannot bring a private claim to enforce Medicaid's equal access provision—even when the state's reimbursement rates are so low that Medicaid beneficiaries' access is affected.[133] Given that Medicare has more secure political support than Medicaid, it is even more evident that political bodies are more hesitant to impose rules that lead to constricting access, making Medicare even more attuned to public wishes.[134]

Thus, Medicare has become a public program that can be defined by its *Goldilocks* nature—it must be efficient and cost-effective so as to secure its support from its public funders (the public and Congress), but must not be so lean and cheap such that it drives providers and institutions away from participation. In effect, Medicare has to act like a private insurance company—one that insures beneficiaries that no private insurance plan typically would—in that its reimbursement rates must be sufficient for provider participation, but it must maintain its bedrock fidelity to the public taxpayer who covers the cost of the program. This challenge serves as a notable tension in the program's architecture.

### *C. Medicare's "Free Market" and Fragmented Regulation*

For providers, the unique regulatory structure of Medicare can serve as a soft push. When the federal government wishes to shift practice patterns, it relies on Medicare's often submerged[135] financial incentives and encouragement, and not hard mandates.[136] The regulatory project of Medicare begins to resemble a

*in Ensuring Access to Dental Health Care for Children in the District*, GEO. U. O'NEILL INST. FOR NAT'L & GLOB. HEALTH L. (Mar. 9, 2018), https://oneill.law.georgetown.edu/death-from-a-toothache-the-story-of-deamonte-driver-and-where-we-stand-today-in-ensuring-access-to-dental-health-care-for-children-in-the-district/. Before Driver's death, about 1/3 of Maryland's Medicaid-covered children had access to dental care. *Id.*

132. *See* Rebecca Beitsch, *Are Medicaid's Payment Rates So Low They're Discriminatory?*, PEW STATELINE, Sept. 22, 2017, https://www.pewtrusts.org/en/research-and-analysis/blogs/stateline/2017/09/22/are-medicaids-payment-rates-so-low-theyre-discriminatory; Tiffany N. Ford & Jamila Michener, *Medicaid Reimbursement Rates Are a Racial Justice Issue*, COMMONWEALTH FUND (June 16, 2022), https://www.commonwealthfund.org/blog/2022/medicaid-reimbursement-rates-are-racial-justice-issue (noting that Medicaid's low reimbursement rates for hospitals amounted to a $24.8 billion underpayment and that "increasing Medicaid primary care rates by $45 per service would reduce access-to-care inequities by at least 70 percent").

133. *See* Armstrong v. Exceptional Child Center, 575 U.S. 320, 322 (2015).

134. Mira Norton et al., *Medicare and Medicaid at 50,* KAISER FAM. FOUND. (July 17, 2015), https://www.kff.org/medicaid/poll-finding/medicare-and-medicaid-at-50/.

135. Suzanne Mettler, THE SUBMERGED STATE 14 (2011) (positing the phenomenon that Americans are often unaware of the public goods upon which they rely and are benefitted).

136. *See* OFF. OF THE NAT'L COORDINATOR FOR HEALTH INFO. TECH., U.S. DEP'T OF HEALTH & HUM. SERVS, FEDERAL HEALTH INFORMATION TECHNOLOGY STRATEGIC PLAN 2011–2015 at

product of technocratic engineering, like a system of dials and switches, all geared to incentivize the right kind of provider behavior. Yet, it lacks hard law sanctions for poor management or health care delivery.[137]

An example of this new reimbursement model featuring value-based reimbursement was prominently ushered in by the Medicare Access and CHIP Reauthorization Act of 2015.[138] Under a component part of this law, called the Merit-Based Incentive Payment System ("MIPS"), Medicare's Part B reimbursement structure was reorganized. The new structure pays providers based on their performance on four important criteria: quality, cost, promoting interoperability, and improvement activities.[139] Failure to excel at these criteria simply means less reimbursement, while succeeding means bonuses.[140] Medicare's regulation carries no hard law penalties for failing to achieve the policy goals of the program, but reduces a provider's profit under the program.[141] If the provider chooses to prioritize their Medicare reimbursement amounts, they will shift their behavior to protect those payments.[142]

A reality of this kind of "free market" regulation highlights the voluntariness of the Medicare program, as mentioned above,[143] but also illuminates the fragmented nature of the regulatory structure.[144] In short, the good of health care creates the need to regulate the practice of medicine from a holistic perspective, but Medicare does not have the universal structure in place to do so. Cash only[145] providers, for instance, are beyond the reach of the Medicare regulatory structure.[146] Even encounters that solely feature private actors—both a private provider and private payer—are outside the natural fit of Medicare regulations.[147]

4 (2011), https://www.healthit.gov/sites/default/files/utility/final-federal-health-it-strategic-plan-0911.pdf.

137. *See* CTRS. FOR MEDICARE & MEDICAID SERVS., MEDICARE FRAUD & ABUSE: PREVENT, DETECT, REPORT 5 (2021), https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/Fraud-Abuse-MLN4649244-Print-Friendly.pdf.

138. Peter S. Hussey et al., *The Medicare Access and CHIP Reauthorization Act: Effects on Medicare Payment Policy and Spending*, 36 HEALTH AFFS. 697, 697 (2017).

139. *See Understanding Medicare's Merit-Based Incentive Payment System (MIPS)*, AMA, https://www.ama-assn.org/practice-management/payment-delivery-models/understanding-medicare-s-merit-based-incentive-payment (last visited Feb. 4, 2023) (explaining the four metrics).

140. *Id.*

141. *Id.*

142. *See* CTRS. FOR MEDICARE & MEDICAID SERVS., *supra* note 137, at 9.

143. *See* Jost, *supra* note 75, at 32.

144. *Id.* at 9.

145. *See, e.g.*, Haley Sweetland Edwards, *What Happens When Doctors Only Take Cash*, TIME (Jan. 26, 2017, 6:46 AM), https://time.com/4649914/why-the-doctor-takes-only-cash/ (noting that "thousands" of "cash-based primary-care practices" have opened across the United States).

146. *Id.*

147. *Id.*

Another policy-based solution example can be Medicare's somewhat controversially[148] successful[149] Hospital Readmissions Reduction Program ("HRRP"), created under the Affordable Care Act ("ACA").[150] This program penalizes hospitals that readmit a patient within thirty days of the initial admission related to certain health indicators.[151] The goals of the program are laudable. The HRRP seeks to link payment to quality and to incentivize "hospitals to improve communication and care coordination efforts to better engage patients and caregivers on post-discharge planning."[152] Nonetheless, nearly half of all the nation's hospitals had their payments cut following the tenth edition of the readmission penalty program, highlighting the ongoing struggle to rein in readmissions.[153]

Medicare's focus in the HRRP has been limiting cost growth and improving systemic quality,[154] even while more than 2,000 hospitals are exempt from HRRP—including those specializing in children, veterans, or psychiatric patients.[155] Some hospitals—just by virtue of the policy design of the program, or the policy preferences of officials[156]—are not subject to the penalties meted

148. *See* Christopher Ody et al., *Decreases in Readmissions Credited to Medicare's Program to Reduce Hospital Readmissions Have Been Overstated*, 38 HEALTH AFFS. 36, 43 (2019).

149. *See* Andrew M. Ibrahim and Justin B. Dimick, *A Decade Later, Lessons Learned From the Hospital Readmissions Reduction Program*, JAMA, May 31, 2019, at 1, 1 (noting the early reports that the program was a "successful pioneer in alternative payment models" and that it significantly reduced readmission rates).

150. *See Hospital Readmissions Reduction Program (HRRP)*, CTRS. FOR MEDICARE & MEDICAID SERVS., https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/HRRP/Hospital-Readmission-Reduction-Program (last modified Aug. 8, 2022, 9:02 AM).

151. The program includes readmission rates for particular admissions related to acute myocardial infarction, chronic obstructive pulmonary disease (COPD), heart failure, pneumonia, coronary artery bypass graft (CABG) survey, and elective primary total hip arthroplasty and/or total knee arthroplasty (THA/TKA). *See id.*

152. *Id.*

153. *See* Jordan Rau, *Medicare Punishes 2,499 Hospitals for High Readmissions*, KAISER HEALTH NEWS (Oct. 28, 2021) https://khn.org/news/article/hospital-readmission-rates-medicare-penalties/.

154. *See, e.g.*, Rohan Khera, *Association of the Hospital Readmissions Reduction Program with Mortality During and After Hospitalization for Acute Myocardial Infarction, Heart Failure, and Pneumonia*, JAMA NETWORK, Sept. 28, 2018, at 1, 10.

155. *See* Victoria Bailey, *Study: Consecutive Penalties for Preventable Hospital Readmissions*, REVCYCLE INTE. (Nov. 8, 2021), https://revcycleintelligence.com/news/study-consecutive-penalties-for-preventable-hospital-readmissions. *See also* Cristina Boccuti & Giselle Casillas, *Aiming for Fewer Hospital U-Turns: The Medicare Hospital Readmission Program*, KAISER FAM. FOUND. (Mar. 10, 2017), https://www.kff.org/medicare/issue-brief/aiming-for-fewer-hospital-u-turns-the-medicare-hospital-readmission-reduction-program/.

156. Hospitals in Maryland—the only state in the United States with rate regulation—are exempt from the HRRP "because [sic] an agreement between CMS and Maryland." CTRS. FOR MEDICARE & MEDICAID SERVS., *supra* note 150.

out by HRRP, nor the behavioral incentives that the program brings.[157] This is the case, even though it would seem that all hospitals—or, more specifically, *patients* of all hospitals, like children's or veteran's hospitals—could benefit from a system in which all hospitals are effectively incentivized to avoid unnecessary readmissions. Ultimately, Medicare's policy mechanism remains fragmented.

## IV. GOING FORWARD

That CMS and Medicare have become key targets of the larger deregulatory project is notable, given Medicare's unique regulatory structure.[158] Of course, those in support of regulatory deconstruction may argue that it was the Biden Administration who decided to layer a new vaccination requirement onto a program that was never meant to hold such mandates. It was the chief executive and the Agency itself, they would say, that created this conflict. As Medicare has often been the chief regulatory avenue for the federal government, for multiple generations now, they would be right in that assertion to an extent.[159]

But, the historical structure of Medicare, and its home agency of CMS, makes it such that it is difficult to argue that Medicare's regulatory requirements carry the same draconian effect as other legal fiats. Indeed, Medicare's regulatory reach is not universal.[160] It is a public insurance company for a huge percentage of American citizens, but it has no independent legal authority to order all providers and entities to heed specific regulatory changes.[161] It works within a confining structure.[162]

Instead, in many ways, it works as a private insurance company would, by offering access to a wide swath of beneficiaries to entities and providers.[163] Many providers and entities would say this is merely a semantic difference—that, in effect, Medicare is, for all intents and purposes, a mandatory program. Any provider or entity that wishes to survive in the American health care system must accept Medicare's programmatic requirements—an argument which is understandable, but legally, there is no mandate to participate in the program.[164] As a result, there is no requirement to heed its strictures; providers and entities can simply exit.

In other words, if a hospital does not wish to comply with a novel COVID-19 vaccination requirement, it can exit the program. There is nothing requiring

157. *Id.*
158. *See* discussion *supra* Part III.
159. *See* discussion *supra* Part I.
160. *See* discussion *supra* Section III.B.
161. *See* discussion *supra* Section II.A, III.A.
162. *See* discussion *supra* Part III.
163. *See* discussion *supra* Section III.A.
164. *See* discussion *supra* Section III.B.

America's hospitals to treat Medicare patients.[165] Also notable here is the fact that the COVID-19 vaccination mandate litigation featured *states* as plaintiffs, and not providers or health care entities.[166]

At its core, the location of the deregulatory battle within the Medicare program is a fight over what kind of power the most prominent health care agency in America will be able to harness. This, of course, is what makes the location an interesting development and what makes it unclear how it will ultimately resolve. Given the history with the program, however, it seems unlikely that this battle will migrate. Medicare is likely to remain front and center in the ongoing debate over how much power a federal agency should be allowed to amass.

Implicit in this deregulatory project—the concern that agencies have amassed great undemocratically-checked and unearned power—is the worry that agencies leave the governed without any option but to comply with agency-made requirements. This concern is highlighted by the fact that agencies are not staffed by democratically elected individuals.[167] The concern may be that these agencies are driven by faceless, bureaucratic expertise, and do not show dexterity and responsiveness to the concerns surfaced by the governed.

The concern that agencies have too much power can clearly be ameliorated by giving citizens subject to agency rule the power to decline to participate in the regulatory project. If individuals have a choice as to whether to participate, the concerns seem to be allayed. Of course, by virtue of its unique architecture, that is exactly what Medicare's regulatory platform allows. Those unwilling to be vaccinated under Medicare's rules can simply no longer participate in the Medicare program. Surely a program funded by American taxpayers should be able to impose reasonable, protective guardrails around its reimbursement rules.

Finally, there is something to be said for the ability of Medicare—as an insurance company—to be able to set appropriate conditions of participation and payment on providers and entities that wish to receive reimbursement as part of the program. The vaccination mandate, according to CMS, was designed to protect Medicare's beneficiaries.[168] As the population of Medicare beneficiaries grows, and regulatory pressure mounts to protect this population of beneficiaries, fights over the future of the regulatory state do not show signs of abating.

## V. CONCLUSION

Medicare's regulatory influence and importance in American health care is undeniable and will likely grow as America ages and its elderly population

165. *Id.*

166. *See* discussion and notes, *supra* Section II.A–B.

167. *See* discussion *supra* Section II.C.

168. *See* discussion *supra* Section II.A.

grows. Nonetheless, demographic and agency-centric power will continue to bump up against efforts to deregulate administrative power in the United States. As a result, Medicare will likely be a battleground for the future of regulation in the United States, with all sorts of consequences for the health of all Americans. Beneficiaries should take heed.