Private Control in Medicare's Off-Label Drug Coverage

Elenore Wade*

Every year, Medicare Part D denies thousands of claims for medically necessary prescription drugs, not by accident or error, but by statute. Part D's statutory "compendium restriction" limits coverage of drugs used off-label unless those uses are recommended by the editors of two private drug databases that are functionally inaccessible to the public. The restriction especially harms patients with conditions for which no treatments have been specifically developed or approved, but for which existing FDA-approved medications have become the recognized standard of care, so much so that physicians who didn't prescribe these medications would be subject to malpractice liability.

The diffusion of Medicare Part D decision making across several private actors exacerbates the compendium restriction's inherent problems. Part D is administered exclusively by private insurance companies who receive billions of dollars of direct federal subsidies annually to control patients' access to pharmacy drugs. These private plans routinely issue erroneous denials in pursuit of profit, exploiting the burdensome Medicare appeals process that both deters patients from challenging denials and insulates plans from accountability rather than exposing them to it. Instead of taking a decidedly adversarial position as a regulator of these private companies, HHS instead acts as their business partner, shoring up the justifications for denials and maintaining an atextual position that interprets the restriction as even more stringent than the statute allows.

This Article—the first to thoroughly examine the compendium restriction as a legal provision—examines the provision's text, implementation, and functions and argues repeal of the compendium restriction is a necessary step

---

* Associate Professor of Law, Rutgers Law School. For early and vital contributions, expert input, and advice, I thank Sandra Johnson, Shavonnie Carthens, Lewis Grossman, Sidney D. Watson, Elizabeth McCuskey, Valarie Blake, Heather Walter-McCabe, Jamille Fields Allsbrook, Liz Chiarello, Fred Rottnick, Elizabeth Pendo, Theodosia Stavroulski, Matiangai Sirleaf, Kelly Gillespie, Michael Sinha, Rebecca Wolitz, and the scholars and interlocutors in the Center for Health Law Studies at Saint Louis University and American Society of Law, Medicine and Ethics Health Law Scholars Workshop. Finally, I thank the many healthcare workers and patients who provided keen insight into the impacts of the policies discussed here.

toward realizing the access Medicare's prescription drug coverage program purports to provide.

INTRODUCTION

Jeremiah recently had a lung transplant. While still in the hospital, Jeremiah began taking a three-drug regimen[1]—which includes the immunosuppressant drug mycophenolate sodium—to prevent rejection of his new lungs. Even though the Food and Drug Administration (FDA) has not approved any medications specifically for lung transplant rejection, Jeremiah's treatment is the widely accepted standard of care. His mycophenolate sodium is specifically approved for prevention of kidney transplant rejection—a much more common procedure than lung transplantation—and it's routinely prescribed for people who receive lung, heart, liver, and pancreas transplants.

Jeremiah has Medicare, which covered most of his transplant care costs, including his prophylactic drugs, in the hospital. Jeremiah also pays monthly premiums to a private prescription drug plan in Medicare's voluntary Part D program. After returning from his post-transplant hospital stay, Jeremiah goes to the pharmacy to pick up his medications, and the pharmacist tells him his plan rejected coverage of mycophenolate sodium. When Jeremiah reaches a plan representative on the phone, they confirm the denial and later mail Jeremiah a notice saying mycophenolate sodium is "not a covered drug under Medicare Part D." Neither Jeremiah nor his physician understands this. Jeremiah clearly needs the drug; it's the standard treatment recommended by the International Society for Heart and Lung Transplantation,[2] and it even appears on his plan's formulary—its list of preferred drugs. What's more confusing is Jeremiah's Medicare *did* cover the drug while he was receiving it in the hospital.

After the insurance company confirms the denial, Jeremiah does what the notice tells him to and requests review with a Medicare Part D Qualified Independent Contractor (QIC). Within a couple days of his QIC request, he quickly receives notice that the QIC has confirmed the denial of coverage was proper. Jeremiah then files the appropriate paperwork to have the denial reviewed by a federal Administrative Law Judge (ALJ). He also opens a GoFundMe page to raise money so he can pay for his medication while he waits.

At the ALJ hearing, Jeremiah is alone, but he shows the ALJ a short letter from his doctor explaining why she prescribed the medication, with a few webpages and studies the doctor sent to show support for the treatment. A

---

1. Ali Mrad & Rebanta K. Chakraborty, *Lung Transplant Rejection*, STATPEARLS CONTINUING MEDICAL EDUCATION (2025), https://www.ncbi.nlm.nih.gov/books/NBK564391 [https://perma.cc/FG4E-S4AQ].

2. *Id.*

month later, Jeremiah finds out he lost the hearing. The ALJ agrees with Jeremiah that the denial is life-threatening. But, the ALJ says, her hands are tied. It isn't enough for a drug to be medically necessary; instead, the drug must be prescribed for what Medicare law describes as a "medically accepted indication," which has a special meaning: Jeremiah's specific use of the drug must be recommended by at least one of two private drug databases Jeremiah has never seen or heard of and has no access to. In hopes that the final administrative appeal stage will yield a different result, Jeremiah appeals the ALJ's decision to the Medicare Appeals Council (MAC). Months later, he is still waiting for the MAC's decision. The Medicare website says he can escalate his appeal to federal court, but Jeremiah doesn't know the first thing about filing a federal lawsuit and can't afford a lawyer to help him.

* * *

The rationing mechanism used to deny Jeremiah's medication coverage is known as Medicare Part D's "compendium restriction," an obscure barrier to coverage unique to Medicare Part D, the Medicare prescription drug program.[3] A prescribed off-label use of an FDA-approved medication can be covered under Part D only if the use is "supported by one or more citations included or approved for inclusion" in one of two private drug databases selected by the federal government.[4] Every day, pursuant to this restriction, the companies that administer Medicare Part D plans deny coverage for patients' medically necessary prescription drugs. In some cases, federal law doesn't just allow plans to issue denials like the one Jeremiah received; it requires it. In others, the restriction allows private plans to erroneously manufacture a durable defense against Medicare's requirement to cover drugs when they are medically necessary.

The compendium restriction is a creature of statute—one clause of public law buried under layers of cross-references—but it also represents the perils of privatization of public healthcare finance administration and the problems of an irresolute agency torn between the incompatible goals of enabling public coverage and protection of large healthcare firms whose business relies on denials. Part D is unique among nominally public healthcare programs in that it's entirely privatized, administered by private insurance

---

3. Approximately fifty million people rely on Medicare Part D for prescription drug coverage, in addition to the more than ten million Medicaid-Medicare dual eligibles funneled into Part D for drug coverage since 2005. 42 U.S.C. § 1395w-114(a)(3)(B)(v); *see also* U.S. DEPT. OF HEALTH & HUM. SERVS., OFF. OF INSPECTOR GEN., PART D PLANS GEN. INCLUDE DRUGS COMMONLY USED BY DUAL ELIGIBLES: 2018, at 2 (2018), https://oig.hhs.gov/documents/evaluation/2932/OEI-05-18-00240-Complete%20Report.pdf [https://perma.cc/UHX9-34EG].

4. 42 U.S.C. § 1396r-8(k)(6).

companies who receive direct subsidies from federal Medicare funds.[5] Federal agency investigations routinely find these plans issue erroneous denials in pursuit of profit, counting on patients to abandon their claims at some stage of the burdensome Part D appeals process.[6] In compendium restriction cases, the appeals process does more to insulate private plans from coverage obligations than to ensure Medicare serves its primary purpose of delivering benefits to its enrollees.

The Part D compendium restriction applies when drugs are prescribed for off-label uses—when a medication FDA-approved for one purpose is used to treat a different condition, such as using an immunosuppressant specifically approved for kidney transplant patients in lung transplant patients. Off-label use is common, legal, and often necessary. For example, in the non-prescription context, the U.S. Preventive Services Task Force (USPSTF), the American College of Obstetricians and Gynecologists, and a host of other clinical authorities recommend low-dose aspirin for people at risk of preeclampsia, a life-threatening condition that arises during pregnancy.[7] But that use—widely recognized as the standard of care—is not approved by the FDA. Under Medicare Part D's compendium restriction, medical necessity and established standards of care aren't enough to ensure coverage. Instead, the editors of select proprietary drug databases (or compendia) must hyperspecifically recommend the prescribed off-label use. In Jeremiah's case, his physician would surely have been liable for malpractice had she not prescribed the routine prophylactic regimen Jeremiah's Part D plan rejected, but under the law, that is beside the point.

Because of the compendium restriction, Part D enrollees, especially those with rare conditions or disabilities, face coverage denials despite the availability of evidence-based treatments, including treatments that are not particularly new, complex, or expensive. For many enrollees, then, the

---

5. *See generally* 42 U.S.C. § 1395w-101(establishing that Medicare Part D prescription drug coverage is offered only through private prescription drug plans or Medicare Advantage plans administered by private organizations, subject to federal standards and subsidies).

6. *E.g.*, U.S. DEPT. OF HEALTH & HUM. SERVS., OFF. OF INSPECTOR GEN., SOME MEDICARE PART D BENEFICIARIES FACE AVOIDABLE EXTRA STEPS THAT CAN DELAY OR PREVENT ACCESS TO PRESCRIBED DRUGS ii, 2, 10–12 (2019), https://oig.hhs.gov/documents/evaluation/3141/OEI-09-16-00411-Complete%20Report.pdf [https://perma.cc/FS8U-CPDG].

7. *E.g.*, *Low-Dose Aspirin Use for the Prevention of Preeclampsia and Related Morbidity and Mortality*, AM. COLL. OF OBSTETRICIANS & GYNECOLOGISTS (2021), https://www.acog.org/clinical/clinical-guidance/practice-advisory/articles/2021/12/low-dose-aspirin-use-for-the-prevention-of-preeclampsia-and-related-morbidity-and-mortality [https://perma.cc/N6V9-WV5T] (recommending "low-dose aspirin be initiated between 12 weeks and 28 weeks of gestation (optimally before 16 weeks) and continued daily until delivery," and referring to USPSTF recommendations).

restriction effectively functions as a blacklist because the less common the diagnosis, the less likely it is to merit a mention in one of the private drug compendia. This means Jeremiah's plan rejected coverage of his drug *because* he was a lung transplant recipient;[8] his condition was the justification for shutting the door to coverage for all possible treatments, leaving him struggling to pay for his treatment on his own as though he had no coverage at all. Under the compendium restriction, some disabled patients are denied all available treatments for the very conditions that made them eligible for Medicare in the first place.

The compendium restriction prioritizes private plan profits over health and over meaningful democratic input in the Medicare program. Part D's rigid reliance on compendia creates a uniquely durable administrative barrier to coverage while offering no substantial benefit to patients or the public. It ensnares thousands of people annually in a nearly unwinnable administrative appeals process—about one percent of enrollees successfully appeal their plans' compendium-based denials—in which the U.S. Department of Health and Human Services (HHS) aids private plans by interpreting the restriction's text as even more limiting than the statute allows. HHS has never promulgated regulations on the restriction, so its restrictive interpretation has never been subject to serious public debate. This alignment of HHS with plan sponsors to deny care based on private reference materials is an undemocratic administrative burden that relies on grasping at a standardization that is impossible in reality; even the most well-funded and scientifically rigorous FDA or drug reference materials could never hope to capture every clinically supported use of a drug.

HHS's position in compendium appeals and litigation also shows that privatization is a way of shifting the agency's constituency from the public at large to an industry it otherwise has a responsibility to regulate. Medicare and other social programs are meant to address well-documented "*under*utilization of health care by disadvantaged groups" in the U.S.[9] In congressional testimony in favor of the Part D program in the early 2000s, legislators explained the urgent need for Medicare to introduce a prescription

---

8. Jeremiah's drug is specifically approved for kidney transplant recipients, who constitute more than half of all annual organ transplants—25,498 of approximately 42,800 transplants in 2022—in the U.S. Lung transplants are quite rare. Two thousand six hundred and ninety two U.S. patients received lung transplants in the same year. *2022 Organ Transplants Again Set Annual Records*, UNITED NETWORK FOR ORGAN SHARING (Jan. 10, 2023), https://unos.org/news/2022-organ-transplants-again-set-annual-records [https://perma.cc/KW8W-NCSX].

9. Carol A. Boyer & Karen E. Lutfey, *Examining Critical Health Policy Issues Within and Beyond the Clinical Encounter: Patient-Provider Relationships and Help-Seeking Behaviors*, 51 J. HEALTH & SOC. BEHAV. S80, S81 (2010) (emphasis added).

drug coverage component to provide "relief from the high cost of prescription drugs" and put a stop to people "risking their health by cutting pills in half or having to choose between paying for medicine or paying their rent, electricity, or buying food."[10] Although it has inched toward achieving some of these goals for some people, Part D has also distributed public wealth upward and shifted power over care distribution in the nation's largest public payment program into private hands—in the quest for coverage of a single prescription, Jeremiah received a rejection from his private plan, based on a review of private sources, appealable to yet another private contractor that quickly rubberstamped the rejection. The compendium restriction, from a public and patient interest perspective, is untenable and must be repealed. Moreover, the restriction—devoid of any discussion in the legislative history—isn't justified by any of the post hoc rationales that have been offered in its favor: it fails to reduce drug costs or bolster FDA oversight of drug safety, efficacy, and advertising.

Repealing the compendium restriction would help Part D function more as a social program than as an enabler of denials and delays reliant on opaque, non-medical standards; these are the means by which insurers generate revenue, but they are not democratic or health-promoting. The compendium restriction embodies hidden rationing as a system-wide policy of denying access to beneficial care, and so it affects not only our individual autonomy, but also our political autonomy. The compendium restriction inhibits public understanding of and deliberation on the present and future of Medicare by incorporating proprietary, inaccessible materials into law, and HHS exacerbates this problem when it shields its rationales and restrictive interpretations from public scrutiny. This obfuscation disregards a key tenet of public healthcare finance as a collective social endeavor: that "patients, as citizens, should not be limited to functioning as beneficiaries of healthcare [and] should rather be entitled to function as distributors of healthcare."[11]

Part I of this Article defines and discusses off-label use and describes how the Part D compendium restriction affects—both in text and in practice—coverage of off-label uses. Part II evaluates the law's design and impact on patients, in part by presenting findings gleaned from examining compendium-based denial cases across all stages of the Medicare administrative appeals process and judicial review. Part III engages with

---

10. 149 CONG. REC. H11598-04, H11599 (testimony of Rep. Hooley of Oregon).

11. S. M. R. Lauridsen et al., *The Secret Art of Managing Healthcare Expenses: Investigating Implicit Rationing and Autonomy in Public Healthcare Systems*, 33 J. MED. ETHICS 704, 705 (2007) (contrasting implicit, or hidden, rationing with explicit rationing, that is, a clear statement that a particular drug will never be covered by a public program).

counterarguments and other rationalizations for the restriction and describes how Part D was the culmination of Welfare Reform and Ownership Society politics, which rejected social spending in furtherance of enrollee autonomy and reimagined regulatory agencies as partners to large firms rather than as their adversaries. Finally, Part IV concludes by briefly tying together these threads under a health justice framework and urges a reexamination of the privatization gamble in Part D.

I. PART D'S OFF-LABEL COMPENDIUM RESTRICTION

The Medicare Part D compendium restriction is a statutory provision prohibiting coverage of a broad range of off-label prescription drug uses. The restriction requires a patient to demonstrate support for their prescribed off-label use by presenting evidence from one of two drug databases selected by Congress and HHS. For many patients with conditions that can and should be treated with drugs already on the market, the compendium restriction blacklists them from coverage by virtue of diagnosis rather than based on evidence that their prescribed use is not safe or effective. The compendium restriction stands in contrast to the more adaptable coverage policies of other public programs and is used to justify thousands of coverage denials annually.

A. Defining and Paying for Off-Label Use

Medicare Part D, like most healthcare payers, covers drugs prescribed off-label.[12] *Off-label use*, generally, means use of a drug for an indication (a diagnosis, symptom, etc.), in a patient group, and/or in a dosage or route of administration other than the drug's specific FDA-approved use[13]—for

12. I use the general term "drugs" throughout to refer to prescribed outpatient drugs *and* biologics, which are both included in the Part D coverage scheme. And "Part D" includes drug plans purchased by people who have traditional Medicare or Medicare Advantage, even though some Advantage plans have Part D rolled into a single monthly premium. Off-label coverage in Medicare Advantage (in MA-PD plans) is subject to the same compendium restriction as in standalone Part D plans. *See* 42 C.F.R. § 423.4 (2024).

13. *See Off-Label*, *in* STEDMAN'S MED. DICTIONARY (Wolters Kluwer Health, Inc. 2023) ("Use of a licensed drug for a purpose not approved by the FDA or other governmental regulatory body."). Although Medicare Part D acknowledges dosage variation as within the technical meaning of off-label use, CMS deals with dosage exceptions through a more informal and less strict exceptions process than the coverage definitions that implicate the compendium requirement. This interpretation means patients using off-label doses may obtain coverage through a standard formulary exception rather than encountering the compendium restriction. U.S. CTRS. FOR MEDICARE & MEDICAID SERVS., MEDICARE PRESCRIPTION DRUG BENEFIT

example, using a drug approved to prevent kidney transplant rejection to prevent lung transplant rejection.[14] Prescribed off-label use is not the same as experimental or investigational use of unapproved drugs and is common, particularly in chemotherapy and pediatrics, and in treatment of rare diseases where few or no on-label options exist.[15]

Whether the FDA has approved a drug for a specific purpose "does not necessarily bear on those uses of the drug that are established within the medical and scientific community as medically appropriate."[16] For example, the ACE inhibitor lisinopril,[17] one of the most-prescribed high blood pressure medications in the U.S., is approved for use in adults to treat acute myocardial infarction, heart failure, and hypertension but is commonly prescribed off-

---

MANUAL ch. 6, § 10.6 (2016) ("Also, medically-accepted indication refers to the diagnosis or condition for which a drug is being prescribed, not the dose being prescribed for such indication. Part D sponsors may have dose limitations based on FDA labeling, but an enrollee may request (and be granted) an exception to a dose restriction through the formulary exception process based on medical necessity criteria.").

14. The diagnosis and off-label use in Jeremiah's case are based on the facts of Case v. Azar, No. 1:17CV741, 2019 WL 1261417, at *1 (M.D.N.C. Jan. 3, 2019), *report and recommendation adopted*, No. 1:17CV741, 2019 WL 1597003 (M.D.N.C. Apr. 15, 2019), in which Part D denied coverage for Myfortic, a drug the plaintiff had been taking off-label for four years to prevent rejection of a lung transplant. Myfortic is FDA approved for a single use—rejection prophylaxis after kidney transplant. *Labeling Package Insert—Myfortic* (Mar. 2022), https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/050791s035lbl.pdf [https://perma.cc/B22X-UUBC]. As discussed later, the FDA has since approved a single medication for use in patients with lung transplant rejection, and each of the two compendia has since added lung transplant rejection prophylaxis as an off-label use of Myfortic. For Jeremiah, this would have helped, but for Janel Case, who actually experienced acute cellular rejection of her transplant, HHS might still have rejected her claim because the compendia only list prophylaxis, leaving open the door for HHS to reject the medication's use for treatment of acute rejection.

15. In pediatrics, off-label use is common because most drugs are approved for adult use based on studies conducted in adults. A pediatric patient may be using a drug for its FDA-approved purpose, but outside the patient population for which the drug is approved. Off-label use of approved drugs in the rare disease context is separate from the process of developing "orphan drug" designations. Orphan drug development is the development of drugs *specifically for use in treating a particular rare disease*. Coverage of orphan drugs has its own issues, such as orphan drugs often being covered under public and private benefit plans but with extremely high out-of-pocket costs. *See* Farah Yehia et al., *Predictors of Orphan Drug Coverage Restrictions in Medicare Part D*, 26 AMER. J. MANAGED CARE 289 (2020). Off-label use in the rare disease context is distinguishable in that the drug being used is has already been researched, developed, manufactured, and approved for at least one use. Off-label uses are not generally of drugs specifically developed for treatment of a rare disease and such drugs may or may not be novel or expensive. This is also distinguishable from legal structures that allow companies to market treatments that aren't even generally approved as safe and effective for any use, as discussed in Part X.

16. Weaver v. Reagen, 886 F.2d 194, 198 (8th Cir. 1989).

17. Sold under the brand names, for example, Qbrelis, Zestril, and Prinivil.

label for diabetic nephropathy and migraines.[18] The ubiquitous over-the-counter drug aspirin has dozens of routine off-label uses, including as a prophylactic for preeclampsia and for heart attack in the general adult population.[19] These uses reflect clinical evidence that develops after drug approval.

An off-label use may be the first line of treatment—as in, of course, the case of a diagnosis which has no FDA-labeled treatments—and it may be something a patient tries after on-label treatments have failed, or where on-label treatments are contraindicated because of an allergy, a medication interaction, or other reason. Many off-label uses are recognized as just as necessary as on-label uses. For example, although the FDA has limited capacity to resolve drug shortages, it does track them; and when it does, it considers both on-label and off-label use to measure actual and anticipated need for a drug.[20] Similarly, off-label uses often become the standard of care, so prescribing them is required in the practice of ethical and effective medicine.[21]

Off-label prescribing is common and broadly legal, and the onus to initiate specific use approvals is on pharmaceutical companies. So, drug companies have few financial incentives to pursue additional use-specific approvals after a drug comes to market for one use.[22] Once a drug is on the market, clinicians may prescribe it for any clinically appropriate use, so post-market information about the drug often develops in clinical settings rather than pursuant to trials or other research conducted by the manufacturers themselves.[23] Medical professionals rely on post-market clinical evidence, professional standards, and practical experience in addition to FDA labeling when working with patients to prescribe drugs. For example, almost immediately after the FDA approved a two-drug regimen for medication abortion using the drugs mifepristone and misoprostol in 2000, "the vast majority of providers were [instead] using evidence-based regimens" of the

---

18. *Lisoprinol (Oral), Dosing/Administration—FDA Uses*, MERATIVE MICROMEDEX, last accessed July 15, 2024.

19. *Aspirin (Oral, Rectal), Dosing/Administration—Non-FDA Uses*, MERATIVE MICROMEDEX, last accessed July 15, 2024.

20. C. Lee Ventola, *The Drug Shortage Crisis in the United States Causes, Impact, and Management Strategies*, 36 PHARMACY & THERAPEUTICS 740, 753 (2011).

21. *See, e.g.*, Lewis Grossman, *Criminalizing Transgender Care*, 110 IOWA L. REV. 281, 287 (2024) ("[Off-label] are often supported by significant evidence and constitute the standard of care; that is, physicians would frequently be committing medical malpractice by not prescribing a drug off-label.").

22. William S. Comanor & Jack Needleman, *The Law, Economics, and Medicine of Off-Label Prescribing*, 91 WASH. L. REV. 119, 143 (2016).

23. *Id.* at 140–41.

drugs at different doses and timing than the FDA labeling recommended. These evidence-based uses rendered the on-label regimen "obsolete about the same time it was authorized."[24]

Due to broad professional discretion over prescribing, challenges for patients relying on off-label uses usually arise because of coverage and payment barriers, not legality or even an absence of effective medicines for treating them. If Jeremiah showed up at a pharmacy with enough money to pay for his prescription on his own, he could receive it.

Historically, both public and private payers simply denied coverage of all off-label uses, even as pharmaceuticals became a more substantial part of routine medical care, but that has changed in recent decades.[25] The crises of debt and denied care caused by the longstanding practice of payment for labeled uses rose to the public consciousness during the George H.W. Bush administration, at the behest of cancer patients; in oncology, most chemotherapy drugs are used off-label.[26] The findings of a federal advisory board led to changes: public payers would ultimately be required to cover off-label uses, and the federal government recommended private insurers cover off-label uses recommended in drug reference compendia or supported by medical literature.[27] In plans regulated at the state level, states now prohibit insurers from offering plans that exclude coverage for drugs solely because a prescribed drug is not FDA-approved for a specific use.[28]

As public payers, Medicare, Medicaid, the U.S. Department of Veterans Affairs (VA), and several smaller public programs have developed some coverage rules that address payment for off-label uses. Typically, these rules are coextensive with general medical necessity rules and rely on a physician's professional judgement.[29] And, in public programs, "the decision of whether

---

24. MKB Mgmt. Corp. v. Burdick, 855 N.W.2d 31, 78.

25. Melody L. Harness, Note, *What Is Experimental Medical Treatment: A Legislative Definition Is Needed "Experimental" Medical Treatment*, 44 CLEV. ST. L. REV. 67, 72–73 (1996); Pub. L. No. 101-508, 104 Stat. 1388 (Nov. 5, 1990) (Medicaid); Pub. L. No. 103-66, 107 Stat. 312 (Aug. 10, 1993) (Medicare).

26. *Id.*

27. *Id.*; *see, e.g.*, Weaver v. Reagen, 886 F.2d 194, 198 (8th Cir. 1989) ("FDA approved indications were not intended to limit or interfere with the practice of medicine nor to preclude physicians from using their best judgment in the interest of the patient.").

28. *See, e.g.*, N.D. CENT. CODE ANN. § 26.1–36-06.1(2) (West 2025); CONN. GEN. STAT. ANN. § 38a-518b(a)(1) (West 2025).

29. Physician sovereignty over care is, of course, an issue worthy of serious critique, and not a paradigm that repealing the compendium restriction on its own would challenge. However, I take care here not to manufacture yet another post hoc rationale for the compendium restriction. The compendium restriction doesn't meaningfully regulate physicians, nor was it ever suggested that it intended to. It also certainly doesn't challenge professional sovereignty with respect to patients, but instead merely substitutes which authorities patients are subject to.

or not certain treatment . . . is 'medically necessary'" is a medical decision that does not rest "with clerical personnel or government officials."[30] Although public healthcare programs are often lauded simply for their insurance-like quality of payment provision, they also contain the important, if not fully realized, tenet that a payor's role is to enable care, not to act in interference of it. Coverage of off-label uses consistent with established medical standards enables care in pursuit of this goal, but Medicare Part D eschews medical standards and instead enforces a bright-line restriction against safe and effective off-label uses.

B. The Compendium Restriction as an Off-Label Blacklist

Medicare Part D is deeply flawed due to its privatized design, but Part D enrollees do enjoy some procedural protections against denials of coverage for medically necessary drugs. However, the compendium restriction arbitrarily denies coverage for medically necessary off-label drugs, blacklisting patients based on diagnosis rather than medical evidence and forcing vulnerable enrollees to forgo essential treatments.

1. The Structure of Part D

For nearly four decades after its enactment in 1965, Medicare did not offer a general pharmacy benefit.[31] Medicare enrollees could have a hospitalization covered by Part A and follow-up visits covered by Part B, but this landmark program abandoned them at the pharmacy door. As pharmaceuticals began to play a larger role in healthcare, the problem grew untenable. People who could afford it bought sparsely available supplemental insurance or paid out-of-pocket for prescription drugs, often accruing crushing debt in the process. In response, in 2003, Congress enacted the Medicare Part D program—a voluntary prescription drug coverage program that would begin in 2006.[32]

---

30. Pinneke v. Preisser, 623 F.2d 546, 550 (8th Cir. 1980) (finding state Medicaid agency's initial decision to deny coverage for "transsexual surgery" violated federal law); *see also* Hern v. Beye, 57 F.3d 906, 911 (10th Cir. 1995); Weaver v. Reagan, 886 F.2d 194, 198–99 (8th Cir. 1989) (finding state Medicaid agency could not restrict Medicaid payment for patient's medically necessary AZT despite specific use lacking FDA approval); Meyers by Walden v. Reagan, 776 F.2d 241, 244 (8th Cir. 1985).

31. Specifically, Medicare did not generally cover what it calls "outpatient prescription drugs."

32. Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066; *see also* 149 CONG. REC. H11598-04, H11599 (testimony of Rep. Hooley of Oregon), *supra* note 10.

Millions of older adults and disabled Medicare enrollees—more than fifteen percent of the U.S. population—now have Part D coverage, and so do all poor and low-income people who are dually eligible for both Medicaid and Medicare, pursuant to the Part D legislation shifting all dual eligibles from Medicaid to Part D for drug coverage.[33]

Amid its substantial flaws, Part D has reduced many people's out-of-pocket drug costs over the past two decades, and more than three-quarters of Medicare enrollees have purchased optional Part D plans.[34] Entirely privatized from its inception, Part D is administered by private benefit companies—called "plan sponsors"—for example UnitedHealth, CVS, and Humana—and many of its flaws emanate from this design. Even where a Medicare enrollee has traditional Medicare rather than an Advantage/Part C plan, enrollment in Part D means selecting a private benefit plan subsidized through direct federal payment to the plan sponsor. In Medicare Parts A and B, the federal government is a direct payer, but its role in Part D is to subsidize plans, issue standards, and offer administrative review of private plan decisions. The wonted coverage denial strategy of private plans is enabled rather than remediated by Medicare's own lumbering administrative appeals process, which is controlled by private actors until enrollees reach the third stage of appeals. Despite this privatization, Part D has some social character that distinguishes it from a purely private market pharmacy benefit plan. Although federal law allows plan sponsors to establish preferred drug formularies just like they would for their private market plans, the program requires plans to grant formulary exemptions to cover "medically necessary" prescription drugs for all beneficiaries.[35] But Part D upends its medical necessity rules by enforcing the compendium restriction against coverage of enrollees' medically necessary off-label drugs.

---

33. *See* U.S. DEP'T. OF HEALTH & HUM. SERVS., OFF. OF INSPECTOR GEN., *supra* note 3, at 2.

34. CONG. RSCH. SERV., R40611, MEDICARE PART D PRESCRIPTION DRUG BENEFIT 3 (2023).

35. *E.g.*, U.S. CTRS. FOR MEDICARE & MEDICAID SERVS., R18PDB, MEDICARE PRESCRIPTION DRUG BENEFIT MANUAL ch. 6, § 30.2.3 (2016); U.S. CTRS. MEDICARE & MEDICAID SERVS., FACT SHEET PART D RECONSIDERATION APPEALS DATA – Q1 2024 1 (2024). QIC decisions use the form language: "A Part D plan sponsor must grant an exception whenever it determines that the drug is medically necessary, consistent with the physician's or other prescriber's statement, and that the drug would be covered but for the fact that it is an off-formulary drug." 42 C.F.R. § 423.578(b) (2024).

2. A Diagnosis-Based Blacklist

The Part D compendium restriction limits coverage of off-label uses, except for chemotherapy drugs,[36] to those meeting the definition of "medically accepted indication" in 42 U.S.C. § 1396r–8(k)(6).[37] This section, a cross-reference to formulary requirements for state Medicaid programs, defines medically accepted indication as per se including FDA-approved uses. For off-label uses, the statute employs the compendium restriction, requiring off-label uses to be "supported by one or more citations included or approved for inclusion in any of the compendia described in subsection (g)(1)(B)(i)."[38]

The word "compendia" in the statute refers to clinical references that summarize drug information.[39] Compendium editors compile, summarize, and make recommendations on label information and medical literature, including clinical trials, case studies, and other peer-reviewed research.[40] The Part D statute lists three compendia that may be used to determine whether a drug is prescribed for a "medically accepted indication," but only two—DrugDex and American Hospital Formulary Service-Drug Information (AHFS-DI)—are now in use.[41]

These compendia provide information on FDA-approved and off-label uses, evidence strength, contraindications, and a list of citations to the references—drug labeling information or medical literature—that

---

36. Chemotherapy drugs benefit from a compendium restriction carveout enacted in 2008. Medicare Improvements for Patients and Providers Act of 2008, Pub. L. No. 110–275, § 182, 122 Stat. 2494, 2496 (2008).

37. 42 U.S.C. § 1395w-102(e)(1)(a).

38. 42 U.S.C. § 1396r-8(k)(6).

39. *See, e.g.*, 42 C.F.R. § 414.930(a) (2025).

40. *E.g.*, Letter from Alan Ying, Chief Med. Officer, Thomson Healthcare, to Richard Klasco, Senior Vice President for Med. Aff. and Ed.-in-Chief, Thomson Micromedex (Feb. 13, 2008) (on file with Centers for Medicare and Medicaid Services).

41. 42 U.S.C. § 1396r-8(g)(1)(B)(i). The "DRUGDEX Information System" referred to in the statute is not as readily identified as DRUGDEX after multiple acquisitions of the company that owned it. It is now contained within a series of combined databases called Micromedex, owned by private equity firm Francisco Partners, and it is still typically referred to as DRUGDEX. *See* Laura Kreutzer & Laura Cooper, *Francisco Partners Collects Nearly $17 Billion to Back Technology Deals*, WALL ST. J. (July 12, 2022), https://www.wsj.com/articles/francisco-partners-collects-nearly-17-billion-to-back-technology-deals-11657621800. Furthermore, "the USP-DI [listed at 42 U.S.C. § 1396r–8(g)(1)(B)(i)(II) is] no longer published; Thomson Micromedex has designated Drug Points as the successor to the USP-DI." U.S. CTRS. FOR MEDICARE & MEDICAID SERVS., CAG-00388, AMA-DE COMPENDIUM REVISION REQUEST (2008); *see also* Medicare Program; Revisions to Physician Fee Schedule & Other Part-B Payment Policies, 72 Fed. Reg. 66222, 66303–04 (Nov. 27, 2007) ("Due to changes in the pharmaceutical reference industry, fewer of the statutorily named compendia are available for our reference.").

contributed to the material in the compendium.[42] The editors' processes for evaluating evidence are proprietary. Both are subscription-based resources designed for institutional use, with DrugDex published by Merative—formerly IBM Watson Health, and before that, owned by Thomson Reuters—and AHFS-DI by the American Society of Health-System Pharmacists, published online as part of the Wolters Kluwer Lexidrug platform. Online subscriptions to these services are available only to hospital systems, medical professionals, and certain students or residents, and a print version of AHFS-DI is available annually for approximately $500.[43]

Under the compendium restriction, Part D plans cannot cover an off-label use unless supported by one of these two compendia, regardless of whether medical necessity, safety, or peer-reviewed medical literature support the use.[44] This exclusion applies—as it did in Jeremiah's case—even if the same drug is covered for the same purpose under other parts of Medicare.

For some conditions, no drugs are covered under Part D because compendium editors have not recommended any treatments.[45] This means Part D enrollees can be effectively blacklisted—based on their diagnosis—from Part D's most important benefits. In Jeremiah's case, even though mycophenolate sodium had long been part of the established standard of care for lung transplant patients, the compendium restriction meant Part D did not

---

42. *See* 42 C.F.R. § 414.930(a) (2025).

43. *See AHFS Drug Information® and AHFS DI® Essentials™*, ASHP, https://www.ashp.org/products-and-services/ashp-licensing/ahfs-drug-information-and-ahfs-di-essentials?loginreturnUrl=SSOCheckOnly [https://perma.cc/73BC-9SE4] (the language on the website aims the product towards hospital systems and medical professionals); *Individual Clinicians & Users*, WOLTERS KLUWER, https://store.wolterskluwercdi.com/CDI [https://perma.cc/Q6EN-MLQ2] (before gaining access to products individuals must select whether they are a professional or student or resident); *AHFS Drug Information 2025*, ASHP, https://publications.ashp.org/display/book/9781585287611/9781585287611.xml [https://perma.cc/8HSS-F2B7].

44. *R.S.*, DAB No. M-11-1799, at 5 (2011) ("[T]he Council acknowledges . . . that the enrollee's use of Geodon is medically reasonable and necessary in this case. We do not question that the enrollee has received significant relief with Geodon, nor do we question his physician's judgment in prescribing Geodon. However, the determinative legal issue is whether the use of Geodon as prescribed meets the criteria in the statute and regulations for a medically accepted indication."). Dual eligibles—but only those with *full* Medicaid, as opposed to people who get Extra Help, etc.—*may* be able to obtain coverage depending on how states deal with claims for Medicare beneficiaries, but that still requires exhaustion of the Medicare appeals process because Medicare is the first payer.

45. U.S. CTRS. MEDICARE & MEDICAID SERVS., *supra* note 35, at § 30.2.3. Because compendia are drug references, not disease references, each compendium organizes entries by drug, with each drug having its own entry. *See, e.g.*, *id.* at app. B. The compendia do not include individual diagnosis pages, but there are many diagnoses not listed as on- or off-label uses of any drug. *See id.*

recognize *any* drugs as medically accepted indications for lung transplant rejection prevention. And because the compendium restriction only exists in Part D, Jeremiah enjoyed coverage of both his transplant and his anti-rejection drugs in the hospital under traditional Medicare.

C. Agency Process and Interpretation Exacerbate the Problem

The compendium restriction allows coverage only for off-label uses supported by the two private compendia rather than by general medical literature or other evidence.[46] This creates barriers for patients, who must support their claims for coverage with a closed universe of privately curated evidence often inaccessible without institutional resources. However, the restriction does not on its face appear to capture the sheer volume of off-label uses that are denied coverage in practice. This is because HHS interprets the restriction more broadly than the statute permits, aligning with plan sponsors to defend coverage denials rather than with patients in pursuit of care.

By statute, an off-label use is a medically accepted indication if it "is supported by one or more citations included or approved for inclusion in . . . the compendia".[47] In each of the two compendia used for Part D, the entry for each drug contains citations to the literature supporting the narrative information provided in the entries. In other words, each compendium entry comprises above-the-line and below-the-line material. For example, consider aspirin (although aspirin is available over the counter and thus not likely to implicate Part D coverage restrictions, it's a familiar drug that helps illustrate how compendia present information). In the DrugDex compendium, the entry for aspirin contains fifty-nine citations as numbered footnotes. The reference list comprises a mix of citations to drug labels, manufacturer information, and medical literature. For example, in the DrugDex tab on precautions for aspirin, one precaution is: "Use caution in children with suspicion of viral illness (influenza and varicella) due to risk of Reye's syndrome." This precaution is marked with a footnote.[48]

The footnote in the list of references for the DrugDex entry for aspirin, is a citation to a paper published in *The Journal of Pediatric Pharmacology and Therapeutics* in 2020, titled *Key Potentially Inappropriate Drugs in Pediatrics: the KIDs List*.[49] As with all DrugDex citations, the publication itself is merely cited and not available as an integrated component of the

---

46. *See, e.g.*, Roeder v. Burwell, 197 F. Supp. 3d 887, 892 (E.D. Va. 2016).
47. 42 U.S.C. § 1396r-8(k)(6).
48. *Aspirin—FDA Uses*, MICROMEDEX DRUGDEX.
49. *Id.*

compendium entry. I can view both DrugDex and the linked full text of the cited paper—as well as the AHFS-DI compendium—for free only because my employer, a large public research university with two medical schools, has subscribed to these materials. As discussed later, patients who have the burden to submit evidence supporting coverage do not have it so easy, and HHS will not access these resources on behalf of patients or develop evidence on their own (unless, of course, it is unfavorable to patients).[50]

Given the layout and contents of the reference compendia, then, what would a lay or legal reader likely conclude about what the statute's language requires for a drug to meet the coverage definition? Likely that the statute's requirement that a drug's use be "supported by one or more citations included or approved for inclusion in any of the compendia" means if an off-label use of aspirin contains *support* in a *citation*—that is, a published paper included in the compendium footnote—such a use satisfies the compendium requirement. However, this is not how the compendium requirement works in practice because HHS's interpretation is counter to the statute's plain meaning, disfavoring coverage where even the clearly restrictive statutory language would be more likely to favor it.

HHS's interpretation of the compendium restriction comes entirely through administrative adjudication, guidance documents, and its filings in litigation, and the agency has never promulgated a rule interpreting or implementing the restriction. The administrative appeals process for Part D recipients has four steps after a patient receives a negative coverage determination from their private plan. In each of these, private and then public actors adjudicate appeals according to HHS's interpretation.

The appeals process is multi-layered, starting at the pharmacy counter, where an enrollee receives their first denial of coverage. Patients must navigate through: (1) redetermination internal to their private plan;[51] (2) reconsideration by a private Medicare contractor—called, in Part D, the Qualified Independent Contractor (QIC);[52] (3) a hearing before an ALJ in HHS's Office of Medicare Hearings and Appeals (OMHA);[53] and, finally, (4) a review by the Medicare Appeals Council (MAC),[54] which functions as

---

50. *See Cancer Care Assocs.*, DAB No. M-12-2316, at 3 (2013) (complaining of appellant who submitted a non-full-text version of supportive evidence and denying coverage, noting "[i]t is not possible to decipher the printout without this missing key. The appellant has the burden of proof in submitting evidence in each appeal.").

51. 42 C.F.R. § 423.580 (2024).

52. 42 C.F.R. § 423.600(a) (2024).

53. 42 C.F.R. § 423.2004 (2024).

54. 42 C.F.R. §§ 423.2100, 431.2102, 431.2106 (2024). The Medicare Appeals Council is a division of the Departmental Appeals Board (DAB).

Medicare's internal high court. The first two stages of appeals take a matter of days, and ALJ and MAC decisions can take months to issue. The appeals process is an administrative cascade, with fewer and fewer appeals reaching successive stages, even where an outcome is unfavorable to the patient and success on appeal is likely.[55] Furthermore, once an appeal emerges from private hands and reaches the ALJ stage, both the private plan and the QIC have appeal rights if a decision at any stage is favorable to the enrollee, so patient success at one stage does not guarantee coverage and terminate the process. The MAC, under direction of HHS and Centers for Medicare & Medicaid Services (CMS) or on its own, can also reach down and review favorable ALJ decisions *sua sponte* if no party appeals, and it frequently does so if ALJs follow the text rather than HHS's strict interpretation.[56]

1. HHS's Atextual Interpretation of the Restriction

The compendium restriction requires Part D plans to cover prescription drugs prescribed for "medically accepted indications," defined as FDA-approved uses or off-label uses supported by specific compendia.[57] In medicine, an *indication* is simply a reason to employ some type of medical intervention.[58] The word is ubiquitous in medical settings, and its definition is broad. An indication is "a sign, symptom, or medical condition that leads to the recommendation of a treatment, test, or procedure."[59] *Stedman's Medical Dictionary*—considered an authoritative text in medical settings—defines indication similarly. The term comprises causal, symptomatic, and specific indications and means: "The basis for initiation of a treatment for a disease or of a diagnostic test; may be furnished by a knowledge of the cause

---

55. Administrative appeals are burdensome. Abandonment of an appeal does not necessarily mean a patient does not have grounds on which to do so. *E.g.*, U.S. DEP'T OF HEALTH & HUM. SERVS., OFF. OF INSPECTOR GEN., OEI 09-10-00350, HIGH RATES OF PRIOR AUTHORIZATION DENIALS BY SOME PLANS AND LIMITED STATE OVERSIGHT RAISE CONCERNS ABOUT ACCESS TO CARE IN MEDICAID MANAGED CARE 15 (2023).

56. *See R.S.*, DAB No. M-11-1799, at 3 (2011).

57. U.S. CTRS. FOR MEDICARE & MEDICAID SERVS., *supra* note 35, at 27.

58. Similarly, a contraindication is a reason *not* to use a medical intervention.

59. *Indication*, NAT'L CANCER INST. DICTIONARY OF CANCER TERMS, https://www.cancer.gov/publications/dictionaries/cancer-terms/def/indication [https://perma.cc/8VM9-C3X8].

(causal indication), by the symptoms present (symptomatic indication), or by the nature of the disease (specific indication)."[60]

For example, aspirin might be indicated for high fever—a symptom—even though aspirin does not treat or cure that fever's possibly unknown cause.[61]

But HHS interprets *indication* in the compendium requirement hyper-specifically and restrictively, counter to its medical meaning. The agency vigorously maintains that an off-label use is only a medically accepted indication if compendium editors list an enrollee's specific diagnosis, or disease, as a recommended off-label use of a drug, and it argues the "therapeutic use *headings* in [the relevant compendium] should not be read expansively, but rather strictly."[62] For example, if a patient has acute pain and the compendium entry lists acute pain as a use for a prescribed drug, HHS would not accept this as an indication in favor of coverage because pain is not a specific diagnosis that reveals the cause of a symptom. Similarly, if a drug like Jeremiah's is listed for *prevention* of transplant rejection, HHS would likely not accept such a listing as satisfying the compendium restriction if prescribed to treat *acute* rejection, even though the drug is serving the same purpose—immunosuppression—in both cases. HHS's interpretation means there are many patients whose administrative appeals are unfavorable not because their prescribed drug isn't—in the medical sense—indicated, but because the editors of two private compendia haven't listed the patient's diagnosis in their recommended off-label uses.[63]

Interpreting indication to mean diagnosis—"[t]he determination of the nature of a disease, injury, or congenital defect"—is directly counter to the everyday meanings of two distinct terms.[64] It also means editors of the proprietary compendia are given extraordinary power over patients' care because their narrative decisions are treated as effectively incorporated by

---

60. LIPPINCOTT WILLIAMS & WILKINS, STEDMAN'S MEDICAL DICTIONARY 966 (28th ed. 2023) (defining "indication").

61. To belabor the point: "A fever is not an illness by itself. Rather it is a symptom that something is not right within the body. A fever does not tell you what is causing it, or even that a disease is present. It may be a bacterial or viral infection. Or, it could be a reaction from an allergy to food or medicine. Becoming overheated at play or in the sun can also result in fever." *Fever*, JOHNS HOPKINS MED., https://www.hopkinsmedicine.org/health/conditions-and-diseases/fever [https://perma.cc/SS8Q-P9B8].

62. *See* Tangney v. Burwell, 186 F. Supp. 3d 45, 56 (D. Mass. 2016) (emphasis added).

63. As discussed in Section I.C.4, when compendium editors do list symptoms as recommended off-label indications, HHS argues these entries are in fact *too* vague and thus not covered uses under Part D.

64. LIPPINCOTT WILLIAMS & WILKINS, *supra* note 60, at 531 (defining "diagnosis").

reference into Medicare law.[65] Furthermore, it leads to condition-based blacklisting because coverage is entirely dependent on whether compendium editors recommend an off-label use for a person's precise diagnosis. This interpretation automatically forecloses coverage of all treatment options for many people, especially those with rare diseases that will likely never merit a specific listing in a compendium. HHS has neither formally expressed a rationale for this nor promulgated regulations interpreting the requirement, although it does defend "drug compendia evidence-based expertise" as fundamental to Part D administration.[66]

Beyond its interpretation of *indication*, HHS in Part D adjudications also interprets the statutory requirement that an off-label use be "supported by one or more citations" included in the compendia. Once again, because of its de facto incorporation of the narrative content of the compendia into law, HHS employs a hyper-restrictive approach to interpreting whether a drug is prescribed for an indication "supported by" the reference compendia, focusing on direct compendium support rather than—as the text demands—support in the literature cited by the compendia. This refusal to follow the text of the law forecloses coverage for many enrollees because support from the underlying literature is far more likely to lead to coverage than is a singular focus on editorial summaries. The underlying literature is far more detailed than above-the-line compendium text. The literature cited in the compendia delves into the clinical justifications for using a certain drug, as well as outcomes in various patient groups, and thus supports the use of drugs in more contexts than the compendia list explicitly.

The agency's refusal to consider the compendium literature disfavors coverage, not only blowing past the underlying citations which are plainly referenced in the Part D statute but also making coverage decisions in accordance with each compendium's proprietary rating system for recommendation and effectiveness. Although the near-universally relied upon Part D guidance—CMS's *Medicare Prescription Drug Benefit Manual* and *Medicare Benefit Policy Manual*—does not explicitly list these ratings

---

65. This Article does not advance a specific argument about whether there is, indeed, a constitutional "doctrine of private nondelegation" and whether HHS's deference to compendium editors violates it. *See* Alexander Volokh, *The Myth of the Federal Private Nondelegation Doctrine*, 99 NOTRE DAME L. REV. 203, 203–07, 237–39 (2023). However, this Article does discuss how this de facto delegation affects patients' interests in compendium-based denials.

66. *See R.S.*, DAB No. M-11-1799, at 3 (2011).

or require minimum ratings for non-cancer drugs, the MAC treats them as incorporated in the fourth and final stage of Part D appeals.[67]

Although HHS could view itself as a regulator of plans with a mandate to ensure plans are not issuing erroneous denials, HHS's interpretation of the compendium restriction instead intervenes in appeals on the side of private plans rather than patients. At all stages and opportunities for interpretation, the agency reads the statute as maximally restrictive and against coverage. It vigorously defends this pro-denial position on appeals, even where patients provide direct support for coverage form literature cited in the compendia.

2. A Pattern of Judicial Deference to HHS's Atextual Interpretation

Judicial deference to HHS exacerbates the compendium restriction's consequences and increases the durability of denials. Because compendium cases usually don't involve a factual dispute about whether the patient's use is medically necessary, courts have typically approached compendium-based denials as legal questions turning on interpretation of the compendium restriction. And *Chevron* deference has shielded HHS's interpretations from detailed scrutiny, in part because of the undue presumption of statutory ambiguity HHS has enjoyed at the first step of *Chevron* analysis in compendium cases. However, in light of the Supreme Court's overruling of *Chevron* in *Loper Bright Enterprises v. Raimondo*,[68] there is reason to think challenges to HHS's interpretation are especially timely. This is especially so because the interpretation described in the previous Section is of an arguably unambiguous statute that lends itself to traditional text-based analysis.

In a limited body of case law,[69] federal courts have addressed two types of challenges to the compendium restriction and HHS's policies: (1) assertions that compendium rule is merely one of several ways to demonstrate coverage,

---

67. *E.g.*, S.A.B., 2009 WL 10822396, at *3 (Dep't of Health & Hum. Servs. Dec. 11, 2009) (finding Part D beneficiary's use of drug "not supported . . . in any of the drug compendia" because diagnosis treated was not listed in non-FDA uses in DrugDex, and DrugDex's rating for use of the drug for patient's secondary diagnosis, which was listed under non-FDA uses, was "Class III," without examining any citations included in the compendium).

68. Loper Bright Enters. v. Raimondo, 603 U.S. 369, 407 (2024).

69. Although judicial review is available after a Part D enrollee exhausts the four-stage Medicare appeals process, most cases are abandoned well before that for lack of resources and time, ill health of the patient, etc. If a patient does exhaust, there are additional barriers to judicial review, for example, lack of counsel and the amount-in-controversy requirement. Thus, reported case law on the compendium restriction is limited.

not a strict requirement, and (2) disputes over HHS's statutory interpretation or fact-finding.

Courts largely reject the first challenge, affirming compendium as a bright-line restriction; although patients would certainly benefit from a more flexible approach, a ruling that the restriction is indeed a firm one is consistent with the admittedly complicated statutory structure.[70] A notable exception, the district court in *Layzer v. Leavitt*,[71] did find that compendium support is only one path to coverage, but its reasoning has been appropriately disregarded by other courts. One might forgive the district judge for seeking a way out of the compendium restriction after hearing the evidence in the case. In *Layzer*, a patient with a rare form of ovarian cancer challenged a denial of coverage for a drug that had slowed her tumor growth and prevented tumors from hemorrhaging.[72] Her physician "warned that the medicine 'is essential for my patient. There is no substitute at this time. Furthermore, if the medicine is stopped, even tempor[ari]ly, it is likely that the remaining tumors will grow quickly and she will suffer grave consequences.'"[73] In addition to the patient's demonstrable need for the drug, the district judge focused also on how reading compendium support as a firm requirement was an affront to canons against interpreting statutes in a way that leads to "untenable distinctions and unreasonable results."[74] To the judge, it was untenable and unreasonable that Medicare Part D would "preclude[] coverage of effective yet newly discovered prescription drug treatments—particularly for rare diseases—because FDA-approved uses often lag behind knowledge about actual effective treatment."[75] Nonetheless, because of the compendium restriction, this is in fact exactly what Part D does.

The second challenge—attacking HHS's interpretation of the compendium provision—has seen some recent successes, although patients

---

70. In a False Claims Act case where a pharmaceutical company disputed the existence of a compendium requirement, a U.S. District Judge in California found the compendium requirement was indeed a bright-line restriction while referring to the relevant statutory sections as "such a complicated maze one would be forgiven for thinking that it was designed to house a Minotaur. Making sense of it requires a long, winding journey through a series of cross-references." United States *ex rel.* Brown v. Celgene Corp., 226 F. Supp. 3d 1032, 1045 (C.D. Cal. 2016); *see also* Nievod v. Sebellius, No. C 11-4134 SBA, 2013 WL 503089, at *10 (N.D. Cal. Feb. 8, 2013) ("[T]he statute at issue certainly is not a model of clarity."); Kilmer v. Leavitt, 609 F. Supp. 2d 750, 755 (S.D. Ohio 2009), *as modified* (Mar. 26, 2009) (the statute "is admittedly unartful in its composition").

71. Layzer v. Leavitt, 770 F. Supp. 2d 579, 587 (S.D.N.Y. 2011).

72. *Id.* at 581–82.

73. *Id.* at 582 (alteration in original).

74. *Id.* at 585 (citing Am. Tobacco Co. v. Patterson, 456 U.S. 63, 71 (1982)); *see also* United States v. Dauray, 215 F.3d 257, 264 (2d Cir. 2000).

75. *Layzer*, 770 F. Supp. 2d at 586.

have, broadly, not been successful at the judicial review stage. Courts typically defer to the strict interpretation described earlier in this Part, either applying the substantial evidence standard to factual determinations in ALJ denials adopted by the MAC or viewing cases as legal matters of statutory interpretation under *Chevron*.[76] There is no settled standard, though, and the degree of deference sometimes conflicts directly with agency regulations stating MAC adjudications are binding only on the parties.[77]

Additionally, in keeping with a judicial reticence to tangle meaningfully with the life sciences, courts have held "the very nature of the Medicare program" and the use of "medical judgment" in HHS's Medicare decisions means that "[w]hen examining this kind of scientific determination, as opposed to simple findings of fact, a reviewing court must generally be *at its most deferential*."[78] Courts also view the Medicare Act[79]—and Social Security Act provisions more generally—as complex because of the voluminous cross-references, long public laws incorporated into an ever-growing Title 42 of the U.S. Code, and the sheer number of programs and activities the statute covers.[80] This leads to courts shying away from rigorous

---

76. *See* Kilmer v. Leavitt, 609 F. Supp. 2d 750, 752–53 (S.D. Ohio 2009), *as modified* (Mar. 26, 2009) (applying the substantial evidence standard of review for Part D drug benefits); Rickhoff v. U.S. Sec'y ex rel. Dep't of Health & Hum. Servs., No. CV-11-2189-PHX-DGC, 2012 WL 6177411, at *2 (D. Ariz. Dec. 11, 2012) (applying the substantial evidence standard used in review of Social Security Administration ALJ decisions); *Kilmer*, 609 F. Supp. 2d at 755–56 (applying *Chevron* and finding statute unambiguously required compendium support but alternatively finding under *Chevron* that, if statute were ambiguous, HHS interpretation that compendium support is required was reasonable).

77. *See, e.g.*, Tangney v. Burwell, 186 F. Supp. 3d 45, 55 (D. Mass. 2016) (citing 42 C.F.R. §§ 405.1048, 405.1130 (2024)).

78. Almy v. Sebelius, 679 F.3d 297, 303 (4th Cir. 2012) (emphasis added) (quoting Balt. Gas & Elec. Co. v. Nat. Res. Def. Council, Inc., 462 U.S. 87, 103 (1983)); *see also* David L. Faigman, *Judges as "Amateur Scientists"*, 86 B.U. L. REV. 1207, 1209–11 (2006). Of course, judges' lack of insight or willingness to gain insight into scientific and medical matters can just as easily lead less to deference and more to overconfidence, but that is rarely the case with compendium issues.

79. "The Medicare Act"—like "the Medicaid Act" courts discuss in Medicaid cases—refers not to a specific public law but to the various statutory sections Medicare law comprises. If an action violates "the Medicare Act," a court is merely saying the action violates lowercase-L "Medicare law," which is scattered across Title 42 of the U.S. Code.

80. *See Organizational Overview*, DEPARTMENTAL APPEALS BD., DEP'T OF HEALTH & HUM. SERVS. (May 19, 2021), https://www.hhs.gov/about/agencies/dab/about-dab/organizational-overview/index.html [https://perma.cc/A2FZ-C72A] ("The Departmental Appeals Board (DAB) provides impartial, independent review of disputed decisions in a wide range of Department programs under more than 60 statutory provisions. . . . The DAB resolves disputes with outside parties such as state agencies, Head Start grantees, universities, nursing homes, doctors, and Medicare beneficiaries. In a single year, disputes heard by the DAB may involve as much as $1 billion in federal grant funds.").

examination of evidence and from challenging HHS's interpretations of even routine medical terms with clear definitions.

In a small number of cases since 2016, courts have begun to press on the faults in HHS's interpretation. In *Tangney v. Burwell*,[81] a patient challenged HHS's interpretations of "supported by" and "indication." Elizabeth Tangney used the drug Dronabinol to treat severe nausea and vomiting after an abdominal surgery. After taking the drug for three years, Tangney enrolled in a Medicare Part D plan, which denied coverage on the grounds that she was not using Dronabinol for a medically accepted indication. Because of the denial, she soon ran out of her drug and "became dehydrated, lost weight, and was hospitalized for three weeks."[82] At the ALJ stage, Tangney received a favorable decision, not because the ALJ found the compendium requirement didn't apply, but because Tangney's use of the drug was indeed *supported by* evidence from the compendia. Tangney had presented to the ALJ a case study of a palliative care patient who used the drug for nausea associated with advanced cancer; the study was cited in the DrugDex entry for the drug. DrugDex cited this study to support its recommendation for the off-label use of the drug in treating "Nausea and vomiting, Disease-related, treatment refractory."[83] DrugDex rated the use as "evidence favors efficacy"—a Class IIb or higher strength of recommendation rating—and listed a strength of evidence rating of "Category C."[84]

The ALJ found the use listed in DrugDex use was sufficiently broad to plainly cover Tangney's use and ordered the plan to cover it. This was counter to HHS's assertions to the ALJ that compendium editors must hyper-specifically list a patient's diagnosis; HHS argued that because the patients in the cited study had *cancer-related* nausea, the citation was not sufficiently supportive of Tangney's use for *non-cancer-related* nausea.[85]

When the MAC took up Tangney's favorable ALJ decision of its own accord,[86] it reversed the ALJ and denied coverage on the grounds that compendium-listed use was in fact *too* general. That is, even though the listed use was for precisely the symptom Tangney's use was addressing (an *indication* within the plain meaning of that word), HHS demanded the compendium list a specific diagnosis to support coverage. The MAC also

---

81. *Tangney*, 186 F. Supp. 3d at 48.
82. *Id.* at 47.
83. *Id.* at 49.
84. *Id.*
85. *Id.* at 51.
86. Her favorable ALJ decision reached the MAC because "Maximus Federal Services, a contractor tasked with reviewing Medicare determinations, petitioned the Council for review of the June decision." *Id.* at 47.

"[a]lthough it is without medical expertise, . . . purported medically to evaluate the Case Study" in the citation and noted that the authors didn't know by precisely what mechanism the drug had worked for the patient and, in any event, the patient's nausea was "cancer-related," which was not the case for Tangney, whose nausea arose after an abdominal surgery.[87]

By the time Tangney's case reached federal court, the district judge reviewed the MAC's decision as a ruling on a matter of law because the parties agreed on the facts of the case—the drug was medically necessary, and the only question was whether the compendium restriction legally prohibited coverage. The judge found that the MAC had failed to adequately substantiate its ultimate legal conclusion. There was no adequate statutory explanation for HHS's requirement that Tangney have the same underlying disease as the patient in the case study because the drug was not purporting to cure that underlying disease. That is, the *indication* for which Dronabinol was prescribed in each case was for a symptom—nausea. Whether the nausea was caused by cancer or complications from surgery didn't matter because the *citation* included in the compendium supported Tangney's use. The trial court ordered Tangney's medication covered. Furthermore, the district judge commended the favorable decision of Tangney's hearing officer because the ALJ had "considered Tangney's real-world history. Specifically, he observed that Dronabinol had worked in treating her symptoms in the past, and that 'without coverage of this drug, [Tangney] will either have to remain in the hospital indefinitely or possibly die.'"[88]

Later, in 2022, the Eleventh Circuit became the first Court of Appeals to issue a rebuke—although it chose to do so in an unreported case—of HHS's maximally restrictive interpretation of the compendium requirement. In *Dobson v. Secretary of Health and Human Services*,[89] the Eleventh Circuit considered a case like *Tangney*. Donald Dobson had tried other drugs to treat his nausea, but none worked, including one to which he had a severe allergic reaction. His doctors also prescribed Dronabinol, and it "worked almost immediately." The court examined the statutory requirement that an off-label use be "supported by" citations in the compendium and—under the first step of *Chevron*—found the provision "not genuinely ambiguous. For that reason, we do not defer to the Medicare Appeals Council's interpretation of the term 'supported by,' and instead must give effect to the unambiguously expressed

87. *Tangney,*186 F. Supp. 3d at 51.

88. *Id.* at 51.

89. Dobson v. Sec'y of Health & Hum. Servs., No. 20-11996, 2022 WL 424813, at *8 (11th Cir. Feb. 11, 2022).

intent of Congress."[90] The court discussed the plain, dictionary definition of the term support, and Congress's failure to express any intention to give the word a different meaning in the compendium provision:

> [T]he phrase "supported by" as used in § 1396r-8(k)(6) therefore requires the conclusion that the compendium citation must *tend to show or help prove* the efficacy and safety of the prescribed off-label use. Nothing about the common meaning of "support" means that a compendium citation must hyperspecifically identify a prescribed off-label use to tend to show or help prove its efficacy and safety.[91]

The court also reviewed the legislative history of public coverage for off-label uses. It traced how the today's compendium requirement directly duplicates the language in the 1993 amendment to Medicare law that added the language to *enlarge*, not restrict, coverage beyond on-label uses. Because the inclusion of the language in the Part D statute more than a decade later happened absent any specific discussion on the measure, the court considered Congress's intent to enlarge coverage in 1993 relevant to the Part D issue.[92] After its success in the Eleventh Circuit, the Medicare advocacy group that represented the patient in *Dobson* brought a similar case on behalf of a different patient. HHS agreed to a settlement and covered the drug.[93] HHS has not, however, indicated it will change its policy for other enrollees in response to these decisions.

The sparse but emerging challenges to HHS's strict interpretation of the compendium requirement suggest a route to challenging its individual effects through litigation. Although the Eleventh Circuit's opinion is unpublished, its reasoning that the statute is not ambiguous and thus does not allow for HHS's interpretation is sound. Especially in light of the Court overruling *Chevron*, HHS should no longer rely on assertions that the statute is any stricter than its plain language indicates. So, litigation may challenge these interpretations in individual cases, but the compendium restriction itself remains a significant barrier not only because it's a coverage restriction generally, but also because it enables spurious denials that remain durable throughout the appeals process.

---

90. *Id.* at *6.
91. *Id.* at *7.
92. *Id.* at *9–10.
93. *Lawsuit Settlement Allows Medicare Coverage for "Off-Label" Medication*, CTR. FOR MEDICARE ADVOC. (June 8, 2023), https://medicareadvocacy.org/lawsuit-settlement-allows-medicare-coverage-for-off-label-medication [https://perma.cc/TRF4-BCA9].

II. STACKING THE DECK AGAINST PATIENTS

The four-stage Medicare appeals process is cumbersome, especially for Part D enrollees, who don't benefit from provider assistance in appeals like enrollees in Parts A and B. Because the burden of persuasion in appeals lies with patients, an initial denial puts an enrollee at a distinct disadvantage given the nature of the evidence that must be presented in compendium cases. Enrollees have no meaningful access to the sources required to prove coverage. Compendium-based denials have strikingly low success rates, attributable in part to how the compendium restriction turns a denial into a legal fight rather than a medical one. Furthermore, despite the federal government's overwhelming documentation of plans' propensities for knee-jerk, inappropriate denials, it defends the quasi-state actions of private entities throughout the process rather than representing the interests of Medicare enrollees.

A. Appealing Denials Is a Lopsided War of Attrition

The very availability of compendium-based denials is favorable to profit-motivated plan sponsors for one primary reason: the restriction allows plans to manufacture a uniquely durable legal presumption against coverage simply by issuing an initial denial. The burden is on the patient to demonstrate coverage, so a denial immediately puts the patient in a disadvantageous position regardless of the merits of their case and begins the war of attrition that is the appeals process. Although other available justifications for plan denials also put patients on the back foot, compendium-based denials are unique because they change the nature of the evidence a patient must present. In most types of Medicare appeals, a patient must prove they do, in fact, need the service in question, but medical necessity is beside the point—and often stipulated to—in compendium cases. HHS and its private contractors work in concert to interpret these evidentiary materials against coverage and ensure written decisions keep patients in the dark about applicable standards.

Federal agencies have repeatedly warned that the profit motive creates incentives to deny claims in all areas where public healthcare payment has come under the auspices of private insurers and managed care plans. And plans have consistently used delay and denial strategies against meritorious claims, resulting in persistent, avoidable delays in care for Medicare enrollees. In a 2017 audit of the Part D programs, CMS cited a staggering 88% of Part D contracts "for at least one violation that resulted in

inappropriate pharmacy rejections."[94] A 2019 report from the Office of the Inspector General found that "Part D beneficiaries experienced up to 84 million rejections when they tried to fill prescriptions at pharmacies."[95]

As a public program, Medicare has more patient protections than typical private insurance. For example, plans may establish preferred drug formularies but must still grant formulary exceptions for medically necessary drugs if there are no suitable on-formulary drugs for a Part D enrollee. And patients have an administrative appeals process that, although far too many cases are drawn into it in the first place, offers patients and providers some process.[96] In light of these protections, issuing a *compendium-based* denial is the best way for a plan to avoid coverage responsibility and maintain that avoidance through multiple stages of appeal. This is because medical necessity is wholly inapposite to disputing a compendium-based denial, putting the patient in a legal battle with their plan rather than a factual one.

In the first place, knee-jerk denial—in general—is an easy choice for plans that don't want to pay for coverage even where that coverage may be required by law because plans count on attrition of cases—that is, patients not appealing denials. A 2014–16 OIG investigation of a sample of Medicare Advantage contracts—i.e., for Part A and B services—found that Advantage plans had denied one million requests for prior authorization and thirty-six million requests for payment for services already rendered in 2016.[97] In part because of the difficult and opaque appeals process, only 1 percent of patients appealed their denials between 2014 and 2016.[98] Of those 1%, though, plans at the first stage of appeal—the reconsideration internal to the plan itself—overturned 75% of their original denials. "The high number of overturned denials raises concerns that some Medicare Advantage beneficiaries and providers were initially denied services and payments that should have been provided. This is especially concerning because beneficiaries and providers rarely used the appeals process, which is designed to ensure access to care

---

94. U.S. DEPT. OF HEALTH & HUM. SERVS., *supra* note 6, at 12.

95. *Id.* at 10.

96. In Medicare Advantage, for example, between 2019 and 2023, more than eighty percent of initial denials of prior authorization were overturned. Jeannie Biniek et al., *Medicare Advantage Insurers Made Nearly 50 Million Prior Authorization Determinations in 2023*, KFF (Jan. 28, 2025), https://www.kff.org/medicare/nearly-50-million-prior-authorization-requests-were-sent-to-medicare-advantage-insurers-in-2023 [https://perma.cc/XKN4-AJN4]. The appeals process, in most cases is working, insofar as Medicare itself is not working as it should.

97. U.S. DEPT. OF HEALTH & HUM. SERVS., OFF. OF INSPECTOR GEN., MEDICARE ADVANTAGE APPEAL OUTCOMES AND AUDIT FINDINGS RAISE CONCERNS ABOUT SERVICE AND PAYMENT DENIALS 2 (2018).

98. *Id.* at 7.

and payment."[99] Of course, relying on the appeals process rather than the program itself to "ensure access to care and payment" manufactures disadvantage for patients.

Quick-trigger denials are a way to weed out patients who don't have the resources to appeal and are a self-serving tactic plans can use to maintain low medical loss ratios—i.e., the proportion of their federal subsidies they spend on payments for patient care as opposed to salaries, bonuses, and other expenses. Furthermore, the appeals process can be viewed as insulating and protecting plans rather than enrollees. The first two stages of Medicare appeals—the only real chance an enrollee has to receive a quick decision—are entirely privatized and controlled by actors with interests in and patterns of denying care. Most people never pursue appeals beyond these stages.

HHS freely acknowledges Part D's privatized model creates these problems, stating "Part D's shared-risk payment model can create an incentive for sponsors to deny requests for prescription drugs in an attempt to increase profits."[100] Plans receive—in general—capitated payments per beneficiary;[101] the proportion of those payments not used to pay for patient care stay in the pockets of the plans. Anyone who uses private-market insurance will be familiar with this problem. Relying on internal standards, plans stand in the way of care. Part D plan sponsors count on low appeal rates and abandonment of appeals due to the long and difficult appeals process, which is made more difficult by patients having to appeal while ill or being denied necessary medication.[102] Plans can strip access to life-sustaining care, then demands their opponents—patients—continue the fight on unequal footing.

For compendium-based denials, plans at the redetermination stage don't tend to overturn themselves, so patients must take their appeals to the second level—reconsideration by a Qualified Independent Contractor (QIC).[103] At

---

99. *Id.* at Report in Brief.

100. U.S. DEPT. OF HEALTH & HUM. SERVS., *supra* note 6, at Report in Brief.

101. There are adjustments to these capitated payments based on risk profile, but capitated payments are by and large similar to premiums. A fixed amount of money comes into the plan, and any claims it pays out eat into the plan's margins.

102. A 2014–16 CMS audit of the Medicare Advantage program "found that beneficiaries and providers appealed only 1 percent of preauthorization and payment denials." U.S. DEPT. OF HEALTH & HUM. SERVS., *supra* note 6, at 6.

103. *See* Consolidated Appropriations Act of 2001, Pub. L. No. 106-554 (2000). The 2001 Appropriations Act incorporated by reference the text of H.R. 5661, the Benefits Improvement and Protection Act (BIPA), which, among other things, added the Independent Review Entity (IRE)/QIC stage of appeals and introduced Medicare reimbursement changes designed to mitigate the deleterious effects of the Balanced Budget Act of 1997. Plans can also change their minds at

the second level, the compendium-based denial continues to enjoy its special durability. The speed of this stage makes it a slightly less onerous obstacle but indicates the QIC level is largely perfunctory in compendium cases. Of the 11,298 Part D plan decisions the QIC reviewed in the first quarter of 2024, they reviewed more compendium-based denials than any other plan denial type by a large margin—4,572, compared to the next-highest number of appeals of 1,899 for formulary exceptions.[104] Of the 4,572 compendium-based denials over those three months, only 55—1.2 percent—resulted in a fully favorable decision for the patient. Two were partially favorable, and 4,515—98.75 percent—were unfavorable.[105]

These high-volume, low-success QIC decisions are, despite the body of evidence the QIC is supposed to consult to make them, rendered quite quickly. Even for non-expedited reconsiderations, the overwhelming majority are decided within six days.[106] The QIC phase is opaque, so it's unclear just how the QIC is processing these requests so quickly if they are also doing so accurately. The independent review involves examining both patient records and compendium entries and—according to law, but not to HHS—the citations supporting the information in those entries to conduct what is essentially a de novo review of whether the drug is covered under Part D.[107] CMS requires patients to place a lot of faith in the accuracy of the QIC, but a brief examination of publicly available QIC data suggests the QIC often gets it wrong. The QIC also crafts its decision notices to avoid providing the patient with information that would help them develop evidence in favor of coverage at subsequent stages.

CMS's searchable list of QIC decisions shows 114 Part D appeal decisions rendered by the QIC on one day: July 18, 2024.[108] Among these decisions are

---

the first stage and retroactively issue a compendium denial, even if the original reason for the denial was different, that is, a formulary exception denial.

104. CTRS. FOR MEDICARE & MEDICAID SERVS., FACT SHEET PART D RECONSIDERATION APPEALS DATA—Q1, 8 (2024), (.zip file containing data downloaded by author via https://www.cms.gov/medicare/appeals-grievances/prescription-drug/reconsiderations).

105. *Id.* at 8.

106. *Id.* at 4.

107. *See* 42 C.F.R. § 423.600(b) (2024).

108. I conducted this search on July 25, 2024. To account for any potential lags in updating CMS's searchable QIC decision website—https://www.cms.gov/medicare/appeals-grievances/appeals-decision-search-part-c-d—I used search parameters to select only Part D decisions, and only decisions from one week earlier—July 18, 2024. As CMS notes on the site, "Some case details aren't included to protect the privacy of the people involved." Decisions, however, always list both the drug for which coverage was requested and the patient's condition(s) for which the drug was prescribed, if the condition was reported in the materials the QIC reviewed. The decision to select a week-old set of appeals was also to avoid any changes in

several compendium-based denials that appear inappropriate even by HHS's strict interpretation of the compendium requirement.[109] Some inappropriately invoke the compendium requirement as a basis for denial when a patient requests an on-label use. For example, on July 18, 2024, QIC reconsideration reviewed a plan sponsor's rejection of the drug Tadalafil to treat a patient's pulmonary arterial hypertension. The QIC issued an unfavorable reconsideration decision, using standard QIC language for compendium-based denials:

> To make our decision, we reviewed all available documentation. In order for a drug to be covered by Medicare Part D, it must be prescribed for a medically accepted indication outlined in the Medicare approved compendia. The use of the requested drug to treat the noted condition is an off-label use. The Medicare-approved compendia do not contain any citations to support the use of the requested drug, as prescribed, for the treatment of this condition. Therefore, the drug is being prescribed for a non-medically accepted indication.[110]

However, the DrugDex compendium, in fact, lists treatment of pulmonary arterial hypertension, in those exact words, as an *on-label* use of Tadalafil, so this should not have been a compendium case at all.[111] Yet, the plan sponsor rejected coverage, leaving the patient to go up to the QIC level, which failed

---

the compendia that may have occurred since an older set of appeals. Because the compendia are electronic databases, additions and changes to listed uses are not dated, so a recent set of QIC decisions avoids the confounding issue of potential updates.

109. CMS does not make the prior and subsequent history of these administrative appeals public, and the explanation of the plans initial decision and redetermination are not summarized on the public QIC website. Thus, it's not possible to determine whether these patients pursued the next stage of appeal. Furthermore, it's not possible to determine whether a plan issued some other, less durable reason for denial before QICs issued a denial. Such information would be useful for understanding the nature and impact of QIC decisions.

110. Appeal Decision, QIC24-449623 (Ctrs. for Medicare & Medicaid Servs. July 18, 2024), https://www.cms.gov/medicare/appeals-grievances/appeals-decision-search-part-c-d?planType=Part+D&sort=desc&appealType=Prescription+Drug&itemService=*&condition=pulmonary+arterial+hypertension&drug=Tadalafil [https://perma.cc/G35V-CFVW]. This language is repeated verbatim, with substitution of the names of drugs and conditions, in each of the QIC compendium-based unfavorable appeals in these paragraphs, unless otherwise noted.

111. *Tadalafil—FDA Uses*, MICROMEDEX DRUGDEX. Although Medicare acknowledges dosage adjustments are medially considered off-label uses, the *Prescription Drug Benefit Manual* carves out an exception for dosage adjustments, allowing patients to use the standard formulary exception process rather than considering such adjustments off-label uses that implicate the compendium restriction. So, it's unlikely any of the publicly available diagnoses are merely attributable to dosing differences. Based on a review of other cases, it's likely the QIC is catching and overturning denials based on off-label dosage or at least reclassifying them as formulary exception rather than compendium cases.

to resolve the issue.[112] On the very same day, another QIC decision shows a compendium-based denial of coverage of Zoryve (roflumilast) cream for seborrheic dermatitis, another word-for-word on-label use of the drug listed in DrugDex.[113] Again, on the same day, the QIC issued a compendium-based denial of the drug Wegovy for a patient whose condition it listed as "Obesity, Heart Disease, And Hypertension."[114] DrugDex lists "[o]besity, [o]r overweight in the presence of at least one weight-related comorbidity" as an on-label use of Wegovy. [115] In another case, the QIC issued a compendium-based denial of the drug Xifaxan for a patient whose condition it listed as "Irritable Bowel Syndrome With Diarrhea."[116] The denial contained the same standard language as all QIC compendium-based denials do, stating all relevant documentation was reviewed independently by a physician. Yet again, "[i]rritable bowel syndrome with diarrhea," in those exact words, is an FDA-approved on-label use for Xifaxan listed in DrugDex.

---

112. The plan sponsor's reason for denial is usually not listed in the publicly available QIC summaries, so it is unclear in these cases whether the compendium was the reason for the initial denial and the subsequent unfavorable review by the plan at the first stage.

113. Appeal Decision, QIC24-449585 (Ctrs. for Medicare & Medicaid Servs. July 18, 2024), https://www.cms.gov/medicare/appeals-grievances/appeals-decision-search-part-c-d?planType=Part+D&sort=desc&appealType=Prescription+Drug&itemService=*&condition=seborrheic+dermatitis&drug=ZORYVE [https://perma.cc/ME6X-79RB]; *Roflumilast (oral/topical)—FDA Uses*, MICROMEDEX DRUGDEX (last accessed July 26, 2024).

114. Appeal Decision, QIC24-449599 (Ctrs. for Medicare & Medicaid Servs. July 18, 2024), https://www.cms.gov/medicare/appeals-grievances/appeals-decision-search-part-c-d?planType=Part+D&sort=desc&appealType=Prescription+Drug&itemService=*&condition=Heart+Disease&drug=WEGOVY [https://perma.cc/KFC8-4LZ3]. *See also* Appeal Decision, QIC24-449605 (Ctrs. for Medicare & Medicaid Servs. July 18, 2024), https://www.cms.gov/medicare/appeals-grievances/appeals-decision-search-part-c-d?planType=Part+D&sort=desc&appealType=Prescription+Drug&itemService=*&condition=obesity+and+atherosclerotic+heart+disease+of+native+coronary+artery+without+angina+pectoris&drug=WEGOVY [https://perma.cc/KFC8-4LZ3] (similar rejection).

115. *Wegovy—FDA Uses*, MICROMEDEX DRUGDEX. Whether or not "obesity" and "overweight" should be, in the first instance, considered *medical conditions*, the federal government and the FDA certainly consider them as such, as demonstrated by the FDA approval information for these drugs, and thus, these QIC denials of drugs plainly approved to treat what the federal government defines as a medical condition were improper. *See* F. Xavier Pi-Sunyer, *Comorbidities of Overweight and Obesity: Current Evidence and Research Issues*, 31 MED. & SCI. IN SPORTS & EXERCISE 602 (Nov. 31, 1999), https://pubmed.ncbi.nlm.nih.gov/10593535/ [https://perma.cc/8JCQ-CX99]; Yizhe Lim et al., *Obesity and Comorbid Conditions*, STATPEARLS (June 27, 2024),

https://www.ncbi.nlm.nih.gov/books/NBK574535/ [https://perma.cc/77A5-SNYE].

116. Appeal Decision, QIC24-449651 (Ctrs. for Medicare & Medicaid Servs. July 18, 2024), https://www.cms.gov/medicare/appeals-grievances/appeals-decision-search-part-c-d?planType=Part+D&sort=desc&appealType=Prescription+Drug&itemService=*&condition=Irritable+bowel+syndrome+with+diarrhea&drug=XIFAXAN [https://perma.cc/23AU-VJYF]; *Xifaxan—FDA Uses*, MICROMEDEX DRUGDEX.

In another case, the QIC issued a denial when the compendia listed treatment of a patient's precise condition as a recommended *off-label* use. On July 18, 2024, a QIC issued a compendium-based denial of the injection drug Ozempic for a patient whose condition the QIC listed as "Nonalcoholic Steatohepatitis."[117] Although nonalcoholic steatohepatitis is not, like in the previous several examples, an on-label use of the Ozempic 2mg dose prescribed to the patient, the DrugDex compendium lists nonalcoholic steatohepatitis as an off-label use. Furthermore, DrugDex rates the strength of this recommendation as Class IIb and the strength of evidence contributing to the recommendation as Class B, similar to its rating for many on-label uses and—according to HHS—a rating that meets the statutory definition of "supported by."[118]

Similarly, the QIC denied coverage when the patient's listed condition was more specific than the one listed in the compendia. This is in keeping with HHS's assertions that a compendium-listed use can be too general to render a use a medically accepted indication. The QIC issued a compendium-based denial of the topical analgesic diclofenac epolamine for "low back pain" even though DrugDex—which lists one on-label use and no off-label uses for the drug—lists "pain, acute" as the on-label use for the drug.[119] Low back pain is, quite obviously, a type of pain. Another decision on the same day denied coverage of the analgesic tapentadol hydrochloride for a patient whose condition it listed as post-laminectomy syndrome.[120] Post-laminectomy syndrome "is a condition characterized by *chronic back or neck pain* following surgery." [121] DrugDex simply lists "pain, acute (severe) and pain

---

117. Appeal Decision, QIC24-449641 (Ctrs. for Medicare & Medicaid Servs. July 18, 2024), https://www.cms.gov/medicare/appeals-grievances/appeals-decision-search-part-c-d?planType=Part+D&sort=desc&appealType=Prescription+Drug&itemService=*&condition=Nonalcoholic+steatohepatitis&drug=OZEMPIC [https://perma.cc/R6N2-JYAS]; *Ozempic—FDA Uses*, MICROMEDEX DRUGDEX.

118. *Ozempic—FDA Uses*, MICROMEDEX DRUGDEX.

119. Appeal Decision, QIC24-449574 (Ctrs. for Medicare & Medicaid Servs. July 18, 2024), https://www.cms.gov/medicare/appeals-grievances/appeals-decision-search-part-c-d?planType=Part+D&sort=desc&appealType=Prescription+Drug&itemService=*&condition=low+back+pain&drug=DICLOFENAC+EPOLAMINE+ [https://perma.cc/8QL6-KB9J]; *Diclofenac Epolamine—FDA Uses*, MICROMEDEX DRUGDEX.

120. Appeal Decision, QIC24-449592 (Ctrs. for Medicare & Medicaid Servs. July 18, 2024), https://www.cms.gov/medicare/appeals-grievances/appeals-decision-search-part-c-d?planType=Part+D&sort=desc&appealType=Prescription+Drug&itemService=*&drug=NUCYNTA [https://perma.cc/6SA9-NG9Z]; *Tapentadol Tydrochloride—FDA Uses*, MICROMEDEX DRUGDEX.

121. *Post-Laminectomy Syndrome*, NOVUS SPINE CTR., https://novusspinecenter.com/pain-conditions/post-laminectomy-syndrome [https://perma.cc/UVV9-KFSG].\ ; Seth A. Waldman,

(severe)" as *on-label* uses without stating any specific cause to which the pain must be attributed, yet the patient still received a denial.

Furthermore, if the QIC solicited sufficient information to make its reconsideration decisions, as required by law, it could avoid outright denials. In one decision, the QIC's explanation lacked information about whether the patient met additional criteria for on-label and off-label uses or how to meet them. The patient requested coverage for the drug Pomalyst (pomalidomide) for a diagnosis the QIC listed as "multiple myeloma."[122] DrugDex and AHFS-DI list Pomalyst as on-label for "[m]ultiple myeloma, in combination with dexamethasone in patients who have received at least 2 prior therapies including lenalidomide and a proteasome inhibitor with disease progression on or within 60 days of last therapy." And DrugDex lists Pomalyst off-label for "[m]ultiple myeloma, [r]elapsed or refractory, in combination with a steroid in a triplet regimen."[123] The QIC is "required to solicit the views of the prescribing physician or other prescriber"[124] during the reconsideration process to ensure they have the information necessary to make an accurate decision, but Part D requires plans themselves to create a file for the QIC, so oftentimes this information comes second-hand. The QIC notes that, "[i]f the case file provided by the Part D plan is insufficient, the Part D QIC is required to solicit the comments of the prescribing physician or other prescriber."[125] The QIC in this case clearly had sufficient information to issue a *denial*, but the file was possibly insufficient to make an *accurate* coverage decision. Instead of issuing a boilerplate denial, the QIC could have created a sufficient record by soliciting information from the physician about whether the patient met the additional criteria for use of the drug.

Each of these patients submitted information into a black box and were told they would receive a thorough, independent review rather than another roadblock, yet they were denied coverage for dubious reasons. For patients who don't abandon their appeals and pursue the next step in the

---

Post-Laminectomy Syndrome, HOSP. SPECIAL SURGERY (Mar. 6, 2024), https://www.hss.edu/conditions_post-laminectomy-syndrome.asp [https://perma.cc/SH9G-56LU] (emphasis added).

122. Appeal Decision, QIC24-449607 (Ctrs. for Medicare & Medicaid Servs. July 18, 2024), https://www.cms.gov/medicare/appeals-grievances/appeals-decision-search-part-c-d?planType=Part+D&sort=desc&appealType=Prescription+Drug&itemService=*&condition=multiple+myeloma+&drug=POMALYST [https://perma.cc/RD82-VHD8].

123. *Pomalyst (Pomalidomide)—FDA Uses*, IBM MICROMEDEX DRUGDEX; *Pomalyst (pomalidomide)*, AHFS DRUG INFO.

124. 42 C.F.R. § 423.600(b) (2024).

125. C2C INNOVATIVE SOLUTIONS INC., PART D QIC RECONSIDERATION PROCEDURES MANUAL 48 (2022), https://partdappeals.c2cinc.com/portals/0/Documents/C2C%20Part%20D%20QIC%20Reconsideration%20Procedures%20Manual_508.pdf [https://perma.cc/6ULV-J9D2].

administrative process, denial at the QIC stage substantially extends the appeals process because decisions take far longer to render at the ALJ and MAC stages. "[W]ith success virtually impossible at the lowest levels of review, beneficiaries must continue their appeals to the ALJ level to have any chance of success. As a practical matter, the lowest levels of review now act as an impediment to obtaining any effective review at all."[126]

At the third stage of administrative appeals—the OMHA/ALJ stage—patients sometimes find a friendlier audience compared to the first and second stages of appeal, but favorable rates are still low. A 2016 GAO report of appeals outcomes in traditional Medicare—where patients are far more likely to get favorable outcomes at multiple stages than they are in Part D cases[127]—found patients at the redetermination, reconsideration, and ALJ stages had, respectively, success rates of 19%, 36%, and 54%.[128] A fifty-four percent success rate at the third stage of traditional Medicare appeals—where, ostensibly, plainly meritorious appeals should have already been filtered out after being resolved in favor of patient and levels one and two—strongly suggests the first two levels are in fact an illusory chance at relief. And, by the time patients receive a favorable ALJ decision, they may have already waited months.[129] Anecdotal, case-based evidence suggests compendium-based denials are occasionally overturned at the ALJ stage, but because plans, patients, and independent review contractors all have appeal rights, even favorable ALJ decisions are often reviewed and reversed once they reach the MAC.

At the fourth level of appeal, the Medicare Appeals Council, as part of the Departmental Appeals Board (DAB), plays an adjudicative role and a broader policy role because of the Secretary's delegation of authority to the MAC to

---

126. *Ongoing Medicare Appeal Concerns & Other Issues*, CTR. FOR MEDICARE ADVOC. (Apr. 11, 2014), https://medicareadvocacy.org/april-2014-ongoing-medicare-appeal-concerns-other-issues [https://perma.cc/J237-NGAY].

127. *See, e.g.*, U.S. DEPT. OF HEALTH & HUM. SERVS., OFF. OF INSPECTOR GEN., IMPROVEMENTS ARE NEEDED AT THE ADMINISTRATIVE LAW JUDGE LEVEL OF MEDICARE APPEALS 23 (2012), https://oig.hhs.gov/oei/reports/oei-02-10-00340.pdf [https://perma.cc/4KVX-RRFJ].

128. U.S. GOV'T ACCOUNTABILITY OFF., GAO-16-366, MEDICARE FEE-FOR-SERVICE: OPPORTUNITIES REMAIN TO IMPROVE APPEALS PROCESS 21 (2016).

129. Unlike the first and second stages, the OMHA/ALJ and MAC stages permit longer timeframes for decision. Moreover, these time limits are often exceeded. There are seventy-seven ALJs within OMHA and six AAJs (Administrative Appeals Judges) who handle MAC decisions within the DAB. *Id.* at 7, 18. The average processing time for appeals in FY 2023 was 137 days, down from a peak of 1430.1 days in FY 2020. *See* OFF. MEDICARE HEARINGS & APPEALS, *Average Processing Time by Fiscal Year*, U.S. DEPT HEALTH & HUM. SERVS. (Apr. 8, 2025), https://www.hhs.gov/about/agencies/omha/about/current-workload/average-processing-time-by-fiscal-year/index.html [https://perma.cc/CS7W-YSH2].

make final agency decisions in Part D cases.[130] If an ALJ issues a decision favorable to a patient, the Secretary can order the MAC to review it.[131] The MAC then announces the policy and interpretation of HHS that, along with HHS's declarations in court filings, forms the basis for judicial review after administrative appeals are exhausted.[132] The MAC is operating as HHS, under—of course—HHS's strict interpretation of the compendium requirement, so even a favorable ALJ decision that relied on anything other than the strict text of the compendium is likely to be reversed by the MAC, requiring the patient to seek judicial review.

There are also evidentiary limits that prevent patients from adding to the record between ALJ and MAC review. This is a problem because, for patients who may be able to demonstrate coverage, a detailed ALJ opinion that explained the compendium requirement was likely their first opportunity to understand how the compendium restriction works and what evidence is required in compendium cases. The MAC requires patients to show good cause to submit new evidence at the MAC stage, and the good cause exceptions listed in HHS regulations require proof that, for example, "unusual, unexpected, or unavoidable circumstance beyond [the patient's] control," such as "[i]mportant records were destroyed or damaged by fire or other accidental cause."[133] These regulations don't seem to contemplate that patients might submit something other than additional medical evidence and may instead want to deploy information from the ALJ's decision to submit compendium evidence in their appeals.

Even when appeals are winnable, a favorable outcome can be a pyrrhic victory because of the constant, repetitive utilization management imposed by plans. A successful appeal and a grant of coverage do not create law of the case that benefits the patient prospectively. So, a patient who makes it all the way through to a successful appeal of a prior authorization denial for one month of medication may have to turn around and do the same thing the next month. On occasion, patients who succeed on judicial review have also sought additional declaratory and injunctive relief ordering HHS take action to ensure contractors and ALJs acted within the bounds of the law in the future. But such prospective relief is precluded by law.[134] But Medicare law "demands the 'channeling' of virtually all legal attacks through the agency,"

---

130. *See* 20 C.F.R. § 404.970(a)(4) (2024) (the MAC "will review a case . . . on its own motion if [t]here is a broad policy or procedural issue that may affect the general public interest").

131. *See* 20 C.F.R. § 404.970(a)(1)–(5) (2024).

132. *See, e.g.*, 42 C.F.R. § 423.2136(d)(1) (2024).

133. 20 C.F.R. § 404.970(b)(3)(iii) (2024).

134. Porzecanski v. Azar, 316 F. Supp. 3d 11, 22 (D.D.C. 2018).

and thus the patient is required to challenge every individual coverage determination—that is, every single time patient tries to fill a prescription—as a distinct agency action requiring administrative exhaustion.[135] The mere availability of compendium-based denials can lock even successful patients in an endless cycle of appeals. Compendium-based denials demonstrably offer plans a durable means of denying coverage, even where those denials are legally incorrect. This undermines patients' interest in drug coverage and undermines Part D's goal of making drugs more affordable for Medicare recipients. The special durability of compendium denials is compounded by asymmetric access to the materials needed to pursue an appeal.

B. Compendia and Related Materials Are Incorporated but Not Accessible

Were HHS to harmonize its interpretation of the statute with the plain text, the compendium restriction would persist as a barrier to coverage because patients would still lack access to the materials needed to pursue favorable appeals of compendium-based denials. The compendia and the cited medical literature—scattered throughout various publications—are all materials privately owned by various publishers. Furthermore, the materials are almost exclusively accessed online, and some are only available to people in certain professions or on an institutional subscription basis.

Those who critique the compendium requirement often rely on precisely this access argument, and patients have noted these issues in court filings.[136] Most of these critiques argue the requirement and current practice deny patients due process because they unduly demand patients present supportive information from sources that are entirely proprietary. A Medicare advocacy organization has called for HHS to "establish a process whereby all beneficiaries, their providers and their advocates, have access to the three [now two] compendia," and for this process to include a requirement that

---

135. *Id.* (quoting Shalala v. Ill. Council on Long Term Care, Inc., 529 U.S. 1 (2000)).

136. Brief of Plaintiff-Appellant at 10, 11–12, Bruce v. Azar, 826 F. App'x 643, 644 (9th Cir. 2020) (citing Aloi v. Azar, 337 F. Supp. 3d 105, 107 (D.R.I. 2018)) ("HHS stated in D.C. [district court] that approx. $400.00 outdated 2016 compendium should be purchased by Mr. Bruce on Amazon.com rather than provide access to the current electronic Compendia. Recently, HHS represented to another D.C. that the same (or 2015) compendium HHS told Mr. Bruce to buy through Amazon.com was too outdated to be relied upon.") ("The MAC states that off-label uses are from Medicare Compendia known as AHFS-DI, or DrugDex, or USP-DI or its successor. No Compendia has been produced except for a partial Micro-DrugDex entry for Serostim and a formulary which is used by Envision. In December 2019, Mr. Bruce checked the costs of DrugDex now owned by IBM and found each year online subscription was $2,000 to $3,000.").

plans explicitly state in denial notices that the reason for the denial is that the proposed use is an off-label use.[137] Now, each plan crafts its own notices, and plans don't often make their reasons plain, stating in compendium-based denials something along the lines of "the drug must be used for a medically accepted indication as defined in § 1860(D)-2(e)(4) of the Social Security Act."[138] Advocates have also called for a burden-shift, requiring the plan sponsor to certify that they have in fact viewed the relevant compendium materials and that there is no support for the use in the compendia, along with penalties for plans that repeatedly violate such a certification requirement.[139]

The access issues are especially problematic because HHS's interpretation effectively claims that Congress has incorporated by reference the text of the two approved drug compendia. When HHS refers to the *narrative text* of DrugDex and AHFS-DI as authoritative, it hands the compendium editors at least some legislative power without ensuring public access while the agency clings to its insistence that the compendium editors make law. Even in non-healthcare contexts with more well-resourced and specialized parties than the scores of pro se patients pursuing Part D appeals, industry actors have complained of lack of access to proprietary materials incorporated by reference (IBR) into law.[140] The compendium context is worse because the compendia are not, in fact, formally incorporated by reference into Medicare law the way other industry standards—often produced by trade associations—are. Thus, federal requirements that IBR materials may only be deemed incorporated if they are "reasonably available to the class of

---

137. *CMA Report: Medicare Coverage for Off-Label Drug Use*, CTR. FOR MEDICARE ADVOCACY, Sept. 16, 2010, https://medicareadvocacy.org/cma-report-medicare-coverage-for-off-label-drug-use [https://perma.cc/R64R-QB4D].

138. These denial notices from plan sponsors are not publicly available. Author has taken this information from a sample of denials personally reviewed by the author, which all included this language. CMS requires plans to use a standard CMS notice form, but the form does not standardize the language plans must use to inform the patient of a substantive reason for denial; it only requires them to list a specific reason for the denial. U.S. CTRS. FOR MEDICARE & MEDICAID SERVS., *Notice of Denial of Part D Prescription Drug Coverage*, Form No. CMS-10146, https://www.cms.gov/files/document/notice-denial-presc-drug-cvgcms101462017fillablev508pdf [https://perma.cc/5F2T-MDTS].

139. CTR. FOR MEDICARE ADVOC., *supra* note 137.

140. Nina A. Mendelson, *Private Control over Access to the Law: The Perplexing Federal Regulatory Use of Private Standards*, 112 MICH. L. REV. 737, 740 (2014) ("To access [worker safety] standards, the CFR refers the reader directly to the ASME at its New Jersey location or at its website. The reader's only alternative is to write for an appointment at the Office of the Federal Register ("OFR")'s reading room in downtown Washington, D.C. On the internet, the cited standard is available from a third-party seller for $68; despite the CFR's promise, ASME itself apparently no longer provides the standard.").

persons affected thereby" do not even apply.[141] Patients are not industry experts and may know nothing about these materials and their role in Part D coverage until they are deep into the appeals process. Once they do learn of the materials, they can't access them, and even with access, procedural rules prohibit them from supplementing the record with information from the compendia.

CMS has referred favorable ALJ decisions to the MAC for review on the grounds that favorable ALJ decisions "challenge[] the integrity of . . . drug compendia evidence-based expertise."[142] In a 2017 case that reached judicial review, an ALJ issued a favorable decision for a patient after the patient presented support for his off-label use from the statutorily authorized American Hospital Formulary Service (AHFS) Pharmacopeia. Although the AHFS compendium did not specifically list the patient's diagnosis, the ALJ found the patient's use clearly supported by citations in the compendium. The patient's physician had presented this evidence from the AHFS compendium published a few years earlier, in 2014.

The MAC reversed the ALJ. It concluded the ALJ's use of the compendium presented a pure issue of law, to wit, "whether an ALJ applied the correct authorities."[143] The MAC found the ALJ had not based its decision on the "*legal authorities* in effect at the time of review," and that a newer version of the AHFS superseded the 2014 version as such a legal authority in the patient's case.[144] The MAC further found there was no support for the use in the most recently published version of the compendium—but only for the same reasons it would have found if it had used the 2014 version.[145] The Secretary maintained this position on judicial review.

Applying the reasoning of other recent cases that have rejected HHS's interpretation, the district judge reversed the Secretary and found the drug covered because the patient's use "was supported by a citation to the relevant compendia" even if the compendium did not specifically list the patient's diagnosis as a recommended off-label use.[146] Furthermore, the outdated compendium was not meaningfully different from the most recently published version. HHS's objection to coverage would have been the same if the patient had presented the 2017 compendium entry.

---

141. *See* 5 U.S.C. § 552(a); 1 C.F.R. §§ 51.1, 51.3, 51.7 (2024).

142. In the Case of R.S., M-11-1799, at 3 (Sept. 8, 2011), https://www.hhs.gov/sites/default/files/static/dab/decisions/council-decisions/m-11-1799.pdf [https://perma.cc/K2J5-PUPF].

143. In the Case of K.A., M-17-6570, at 5 (July 17, 2017) (MAC document located at case no. 1:17-cv-00420-JJM-LDA, ECF no. 1 and on file with author).

144. *Id.* at 6 (emphasis added).

145. *Id.*

146. Aloi v. Azar, 337 F. Supp. 3d 105, 109 (D.R.I. 2018).

Demands for increased access to compendium materials are not problems in and of themselves. Some patients have obviously benefited when they were able to obtain access to compendia to demonstrate coverage. And access is necessary regardless of how strictly the compendium requirement is interpreted. Somewhat perversely, the higher standard HHS has set may lead to less coverage, but it still requires *less* access to compendium information because of its deference to compendium editors' narrative. Under the HHS standard, a printout of a drug's main entry in a compendium is all the information needed—and all that is *permitted*—to decide whether a use is covered. Under the standard imposed by the plain statutory text, patients further require access to the medical literature cited by the compendia.

Access must clearly be improved in the current statutory environment. If patients were required to walk across a bed of hot coals to gain drug coverage, it would certainly seem fair for HHS to provide the coals, but doing so wouldn't justify the requirement itself. Meeting demands for access doesn't solve a fundamental problem of the compendium requirement: its construction of a permission structure for plans to deny medically necessary drugs based on non-medical standards.

C. Contradicting the Standard of Care and Rendering Provider Assistance Useless

It's well understood, even by HHS, that the compendium restriction precludes coverage of medically necessary, evidence-based care. Of course, the compendium restriction doesn't purport to regulate medical practice or drug dispensing itself.[147] When patients have argued it impermissibly does so, HHS's response has been that the restriction is merely a matter of coverage; a physician is still free to prescribe whichever medication they want. But prescribers and patients both have an interest in ordering treatments patients can access in reality rather than in a hypothetical world where payment is not an issue. Because of this, prescribers sometimes consult sources like plan formularies when making care decisions.[148]

In the case of the compendium restriction, however, even consulting a plan's formulary is useless for off-label drugs because the compendia trump

147. *See* Philip M. Rosoff & Doriane Lambelet Coleman, *The Case for Legal Regulation of Physicians' Off-Label Prescribing*, 86 NOTRE DAME L. REV. 649, 653–55 (2011).

148. Of course, although formulary restrictions may be surmountable, they too can be barriers to appropriate care and encountering formulary restrictions draws the ire of physicians who, according to one study, "acknowledged the importance of adhering to formulary prescribing but

the formulary. For example, in Jeremiah's case, not only was his drug medically necessary; it was also on the plan's formulary. In fact, the drug is in a protected therapeutic class—"immunosuppressants for treatment of transplant rejection"—for which Medicare requires plan sponsors to list *all* drugs in the category on their formularies in order to avoid plans delaying vital treatments because of technicalities like requiring patients to litigate formulary exceptions.[149]

The procedural and legal labyrinth of appealing a compendium-based denial is rendered more absurd by how contrived it is. Like many other healthcare financing rules, the compendium requirement is an arbitrary coverage rule in that it "reflects no established medical model of health care."[150] But only in Part D can this special restriction, which is not plain in the statute, override a determination of medical necessity when a patient requests prescription drug coverage. As the MAC has stated, the compendium restriction prohibits even treatment that "reflects the best judgment of the medical community."[151] Although the MAC attributes this to Medicare's status as a "defined benefit program,"[152] it is again only in Part D and only for off-label uses that a drug that is (1) in a class of drugs Medicare covers, (2) on a plan's formulary, and (3) medically necessary gets no coverage because of the *identity of the patient using it*.[153] A coverage standard so

---

are faced with the need to prioritize improving patient outcomes." This was "[c]ombined with participants' belief that as experts in their field, their decisions to prescribe [non-formulary drugs] are justified." Zachariah Nazar et al., *Investigating Physicians' Views on Non-Formulary Prescribing: A Qualitative Study Using the Theoretical Domains Framework*, 45 INT'L J. CLINICAL PHARMACOLOGY 1424, 1430 (2023). *See also* Lauren Vela, *How Physicians Can Help Reduce Wasteful Drug Spending*, THE COMMONWEALTH FUND (Sept. 5, 2019), https://www.commonwealthfund.org/blog/2019/how-physicians-can-help-reduce-wasteful-drug-spending [https://perma.cc/JSZ9-9FHW] ("A majority of the physicians' offices [reported in interviews that they] spend at least 24 minutes a day readjusting prescriptions to be in compliance with formularies.").

149. U.S. CTRS. FOR MEDICARE & MEDICAID SERVS., *Medicare Prescription Drug Benefit Manual*, § 30.2.5 ("Part D sponsor formularies must include all or substantially all drugs in the immunosuppressant (for prophylaxis of organ transplant rejection), antidepressant, antipsychotic, anticonvulsant, antiretroviral, and antineoplastic classes. CMS instituted this policy because it was necessary to ensure that Medicare beneficiaries reliant upon these drugs would not be substantially discouraged from enrolling in certain Part D plans, as well as to mitigate the risks and complications associated with an interruption of therapy for these vulnerable populations.").

150. *See* Blum v. Yaretsky, 457 U.S. 991, 1015 (1982) (Brennan, J., dissenting) (discussing a hospital reimbursement rule in traditional Medicare).

151. In the Case of K.A., M-17-6570, at 4 (July 17, 2017).

152. It doesn't make much sense to refer to a medical assistance program this way, but Medicare does have certain defined restrictions, such as excluding certain prescribed, on-label uses—for example, drugs used specifically for hair growth—altogether.

153. In the Case of K.A., M-17-6570, at 6 (July 17, 2017).

wholly unrelated to medical necessity is untenable as an infringement on patients' interest in coverage and the public's interest in Medicare serving the purpose it claims to have.

Off-label uses are often required by the standard of care, so "physicians would frequently be committing medical malpractice by not prescribing a drug off-label."[154] Therefore, even if a provider used an approved compendium as its exclusive drug information resource to serve a special Part D coverage rule, it would be limiting its ability to provide proper care because consultation with patients, care teams, and other experts, as well as reliance on experience in other cases, are also necessary in ethical clinical decision-making.

Even the process of reaching a specific and accurate diagnosis—certainly an important medical prerogative for many reasons—can threaten Part D coverage because a precise diagnosis, especially a rare one, makes it more likely a patient cannot rely on the compendia to prove coverage. For example, a person diagnosed with multiple sclerosis and successfully treated with off-label, but compendium-recommended, immunosuppressant drugs might later be more accurately diagnosed with the rare autoimmune disorder myelin oligodendrocyte glycoprotein antibody disease (MOGAD). Suddenly, a medically necessary drug they've been using with success for years, which is just as indicated for their previous diagnosis as their current one, is excluded from Part D coverage because there is no mention of MOGAD in the drug's—or any drug's—compendium entry. For disabled Medicare enrollees, this issue is compounded by a requirement to attain expert biocertification of the precise kind of disabled identity that confers eligibility for Medicare benefits.[155] Such biocertification regimes—which impose biological criteria for membership in social categories—require routine recertification and demands for biological evidence of disability. This increases the potential for a precise or differential diagnosis that puts Part D coverage out of reach.

For many rare conditions and associated symptoms, there *are* drugs a competent provider would prescribe. This is borne out in countless cases where patients demonstrate clear medical necessity for drugs but are denied coverage because of the compendium requirement. As one district judge remarked when affirming a denial of coverage, "what was enacted seems unjust on grounds of simple decency to [the patient], whose apparently notably rare condition may *never* lead to coverage . . . under the current

---

154. Grossman, *supra* note 21, at 287.

155. ELLEN SAMUELS, FANTASIES OF IDENTIFICATION DISABILITY, GENDER, RACE 122–26 (2014); *see also* AMANDA APGAR, THE DISABLED CHILD: MEMOIRS OF A NORMAL FUTURE 152 (2023).

statutory scheme."[156] And the compendia do not keep pace with medical knowledge. If Jeremiah's case happened today, he would now find a compendium has recently listed lung transplant as a recommended off-label use of his medication.[157] However, he would have lost his lungs, and possibly his life, waiting for compendium editors to recognize a long-established standard of care for people with no medications specifically approved to treat their conditions.

The compendium restriction's incompatibility with appropriate care is demonstrated by the futility of provider assistance in Part D cases. Part D cases have extremely low rates of provider assistance.[158] Treating physicians often assist patients in appealing denials of coverage for hospital and medical services, and their assistance can be vital because such appeals rely on a medical necessity standard, and patients' own statements are discredited as self-serving and non-expert.[159] When coverage for Part A and B services is denied, providers' own reimbursement is at stake, creating an incentive for providers to pursue appeals, especially where they've already rendered services. Thus, the overwhelming majority of Part A, Part B, and Medicare Advantage appeals are brought by providers.[160]

But providers are, of course, not reimbursed for the pharmacy drugs they prescribe.[161] This leaves patients to pursue Part D appeals alone or with

---

156. Kilmer v. Leavitt, 609 F. Supp. 2d 750, 757 (S.D. Ohio 2009) (emphasis added).

157. *See* Erin N. Lushin et al., *A Multicenter Case Series Documenting Medicare Part D Plan Denials of Immunosuppressant Drug Coverage for Organ Transplant Recipients*, 21 AM. J TRANSPLANTATION 889, 895 (2021) (explaining that expanding immunosuppressant drug access in organ transplants would allow Part D recipients to get an off-label medication for lung transplants).

158. MEDICAID & CHIP PAYMENT & ACCESS COMM'N, REPORT TO CONGRESS ON MEDICAID AND CHIP 23 (2024), https://www.macpac.gov/wp-content/uploads/2024/03/Chapter-2-Denials-and-Appeals-in-Medicaid-Managed-Care.pdf.accreport.pdf [https://perma.cc/9QUR-LALB].

159. *Id.* at 31–32; *see* ELLEN SAMUELS, FANTASIES OF IDENTIFICATION: DISABILITY, GENDER, RACE 17–18 (2014) (discussing the role of the expert in cases of personal identification); *see also* U.S. CTRS. FOR MEDICARE AND MEDICAID SERVS., *supra* note 138. CMS requires plans to use when issuing Part D denials, patients cannot—on their own—direct the plan to expedite an appeal. *Id.* If a patient wants an expedited redetermination—a redetermination with a time limit of 72 hours—the plan will automatically expedite the appeal if the prescriber directly requests it or supports the patient's request. *Id.* But plans inform patients that if they request expedited redetermination on their own, "we will decide if your health requires an expedited appeal." *Id.*

160. *See generally* U.S. GOV'T ACCOUNTABILITY OFF., GAO-16-366, MEDICAID FEE-FOR-SERVICE: OPPORTUNITIES REMAIN TO IMPROVE APPEALS PROCESS (2016) (examining the appeals process for Medicare fee-for-service claims). Medicare Advantage plans with integrated Part D coverage still have the same coverage rules as all other Part D plans, so Medicare Advantage appeals success rates do not cover pharmacy drug appeals; all of those are considered Part D appeals.

161. 42 U.S.C. § 1396r-8(a).

minimal support from providers. In fiscal year 2012, direct Part D appeals by providers constituted less than 1% of all provider-filed Medicare appeals at the ALJ stage, whereas Part D appeals by enrollees made up eight percent of all ALJ-stage Medicare appeals.[162] Even where providers assist patients with Part D appeals, the deck remains stacked against coverage because provider assistance typically involves wielding their expertise to demonstrate the *medical necessity* of treatment. That's not helpful in compendium-based cases. In fact, although Part D success rates are relatively low at the ALJ stage regardless of the identity of the appellant, some appeals data show patients appealing Part D denials on their own are more successful than those with help from providers, whereas the opposite is true in Medicare Part A and B appeals and DME appeals.[163]

Mismatches between standards of evidence-based care and coverage rules were the reason for the original compendium language in other parts of federal law. When prescribers ordered medications their patients needed, coverage that exclusively paid for on-label uses was ensuring only those who could pay on their own would get the appropriate care. Today's compendium restriction—although putatively extending coverage to off-label uses—continues this legacy of unequal care.

III. COUNTERARGUMENTS AND RATIONALIZATIONS

It is, frankly, unclear whether the problems described in Part II were the intent of Congress when it incorporated the compendium language into Part D, but they nonetheless have been the result. And the restriction's favorability to private plans might explain its persistence as well as the outsized number of denials issued according to the restriction. There's no legislative history specifically addressing the Congress's addition of the provision to Part D. All legislative history on the language itself relates to the federal government expressing an interest in the *enlargement* of public coverage to include off-label uses.[164] In the Medicaid program, from which the text of the compendium language is directly borrowed by cross-reference, the language does not restrict coverage. Instead, it provides an example of how states can

---

162. U.S. DEPT. HEALTH & HUM. SERVS., OFF. INSPECTOR GEN., OEI-02-10-00340, IMPROVEMENTS ARE NEEDED AT THE ADMINISTRATIVE LAW JUDGE LEVEL OF MEDICARE APPEALS 23 (2012).

163. *Id.* at 8, 10.

164. *See, e.g.*, Modernizing Part D and Medicare Advantage To Lower Drug Prices and Reduce Out-of-Pocket Expenses, 84 Fed. Reg. 23832, 23832 (May 23, 2019) ("There is also a particular focus in this final rule on strengthening negotiation leverage for MA and Part D plans and increasing competition in the market for prescription drugs.").

determine which off-label uses to add to state formularies. States are required to have formularies that reflect established standards of medical practice, and the compendium language in Medicaid tries to ensure patients using drugs off-label will not be unnecessarily subject to a requirement to pursue a formulary exception for routine off-label uses.

Amid the dearth of Part D-specific rationales for the use of compendium language, HHS has sometimes articulated rationales for the provision when it defends denials. First, HHS has claimed the restriction is foundational to preserving the federal government's—and specifically the FDA's—regulatory authority, which encompasses, generally, making drugs available on the market only when they are safe and effective for at least one purpose. Second, the occasional judge has chimed in too, commenting that the coverage restriction is part of the balance struck between creating a new public program and controlling its costs through managing drug utilization. Even taking these interests as reasonable or compelling, the compendium restriction is a blunt tool for pursuing them, and not an effective one. The federal government's regulatory mandates are not substantially advanced by the requirement. And the cost-containment rationale is simply dishonest. Not only does it ignore that Medicare's purpose is, in fact, to spend money paying for healthcare, but also the compendium requirement does not meaningfully address the real problem of ballooning drug costs in the Medicare program—costs which are passed on to patients as well.

A. Drug Safety

HHS has at times defended its strict definition of the compendium restriction as fundamental to "the integrity of FDA drug oversight authority."[165] The FDA was established, in part, to ensure the safety and quality of drugs.[166] It does this by regulating how drugs are determined safe to come to market, as well as how drugs are labelled and otherwise advertised to providers, pharmacies, and the public. Although regulation and strong premarket approval regimes are vital to drug safety, imposing a uniquely burdensome and medically arbitrary restriction on Part D patients' coverage

165. *In the Case of R.S.*, DAB M-11-1799, at 3 (2011) (internal quotation marks omitted).

166. *What We Do*, U.S. FOOD & DRUG ADMIN. (Nov. 21, 2023), https://www.fda.gov/about-fda/what-we-do [https://perma.cc/U4J6-A85U].

does not serve these goals. At best, it does so in a way that is overinclusive, negligible at scale, and largely accidental.

The FDA's regulatory authority over both drug approval and drug promotion has been weakened over time.[167] This is consistent with a broader consumerism/economism approach, in which—amid a lax regulatory environment—people are expected to be discerning consumers who make individualized choices about cost, benefit, and risk.[168] The FDA has faced well-earned criticism for its deference to industry interests at the expense of individual and population health and the devolution of certain aspects of safety from a public responsibility to an individual one.[169] In recent years, the agency's premarket review process for drugs has offered drug companies more and more pathways to accelerated review, and user fee-based approval programs have "selectively funded only those FDA statutory mandates needed to bring products to market, and not those needed to improve science, conduct postmarket surveillance, or enforce the law."[170]

Newer treatments, or even small modifications to drug delivery or composition, are beneficial to drug companies' bottom lines, as intellectual property regimes and suppression of competition allow new—and not so new—drugs to be sold at the especially high prices drugs draw in the U.S. market.[171] Additionally, once a drug is approved, companies benefit as use increases. Off-label use can have uniquely beneficial margins for drug companies because off-label uses don't require investment in research or petitions for FDA approval, so they expand the market for an already

---

167. *See generally* Daniel G. Aaron, *The Fall of FDA Review*, 22 YALE J. HEALTH POL'Y L. & ETHICS 95, 95 (2023) ("In some cases, premarket review has been so hollowed out that all that remains is the illusion of regulation, nothing more.").

168. *See, e.g.*, John Aloysius Cogan Jr., *The Failed Economics of Consumer-Driven Health Plans*, 54 U.C. DAVIS L. REV. 1353, 1360–64 (2021); Martha T. McCluskey, *Constitutional Economic Justice: Structural Power for "We the People"*, 35 YALE L. & POL'Y REV. 271, 274 (2016); Elizabeth D. De Armond, *A Dearth of Remedies*, 113 DICK. L. REV. 1, 27 (2008); Whitney R. Morgan, Note, *The Prohibition of Moonshine: A Consumer Protection Analysis of Raw Milk in Interstate Commerce*, 117 W. VA. L. REV. 385, 395 (2014); *see also* United States v. Caronia, 703 F.3d 149, 167 (2d Cir. 2012) (internal quotations omitted) ("[I]n the fields of medicine and public health, where information can save lives, it only furthers the public interest to ensure that decisions about the use of prescription drugs, including off-label usage, are intelligent and well-informed. . . . The government's construction of the FDCA essentially legalizes the outcome—off-label use—but prohibits the free flow of information that would inform that outcome.").

169. *See* Aaron, *supra* note 167, at 95.

170. *Id.* at 125–26.

171. Rebecca E. Wolitz, *States, Preemption, and Patented Drug Prices*, 52 SETON HALL L. REV. 385, 425–31 (2021); Dee Gill, *$52.6 Billion: Extra Cost to Consumers of Add-On Drug Patents*, UCLA ANDERSON REV. (Apr. 24, 2024), https://anderson-review.ucla.edu/52-6-billion-extra-cost-to-consumers-of-add-on-drug-patents [https://perma.cc/MG4N-8AM7].

approved drug at low cost to the manufacturer.[172] Because of these incentives, off-label use draws heightened scrutiny of industry motives.[173]

The interests of patients seeking treatments have, at times, converged with those of industry and led to increased pressure on the FDA to get more drugs to market more quickly.[174] Convergence of industry and public interests is sometimes overstated as a true partnership, though. Industry groups cloak themselves in the veneer of patient advocacy, as when the Alzheimer's Association "partnered with [biotech company] Biogen to hire celebrities like Samuel Jackson to create buzz and build public support for approval [of an ineffective Alzheimer's drug]."[175] This enlistment or cynical use of patients presents the FDA as an obstacle to the innovative and life-changing treatments drug companies would be happy to sell to the public if only the government got out of their way.

Drug companies acting in this imagined patient advocacy role have, of course, always pushed for less regulation, not more, as universally better for the public.[176] A recent example of this is the federal "Right to Try" Act, enacted in 2018. Right to Try—which has analogs at the state level—allows the sale of experimental, unapproved treatments to patients who have exhausted other options.[177] As with many deregulatory campaigns, "these Right to Try laws have been carefully crafted to protect every party except the patient."[178] The federal Right to Try law eliminates liability for manufacturers and exempts physicians from liability for ordinary negligence; it also constrains the FDA's authority to consider safety data from these

---

172. *See* Gail A. Van Norman, *Off-Label Use vs Off-Label Marketing of Drugs*, 8 JACC: BASIC TO TRANSLATIONAL SCI. 224, 228 (2023); Steven Findlay, *What You Should Know About Off-Label Drug Use*, MEDSHADOW FOUND. (Sept. 13, 2024), https://medshadow.org/what-you-should-know-off-label-drug [https://perma.cc/U4CJ-GVRG].

173. *See, e.g.*, Rebecca Dresser & Joel Frader, *Off-Label Prescribing: A Call for Heightened Professional and Government Oversight*, 37 J.L. MED. & ETHICS 476 (2009).

174. *See* Aaron, *supra* note 167, at 128–29.

175. *Id.* at 128.

176. *See generally* Kyle James, *Secrets of the Medicine Cabinet: How Big Pharma's Information Monopoly Influences Federal Public Health Regulations*, 16 CULTURE, SOC'Y, & PRAXIS 1 (2024) (examining Big Pharma's lobbying activity in pharmaceutical regulation). However, in the sense that patent and trademark law also involve a type of regulation, the same companies have pursued strong protections against generics and competition.

177. *See* Right to Try Act, Pub. L. No. 115-176, 132 Stat. 1374 (codified as amended at 21 U.S.C. § 360bbb).

178. James Rickert, *On Patient Safety: A Right to Try, Not Exploit*, 479 CLINICAL ORTHOPAEDICS & RELATED RSCH. 1435, 1435–36 (2021); *see also* Susannah W. Lee & Daniel J. Hurst, *Ethical Concerns Regarding Private Equity in Right to Try in the USA*, 21 LANCET ONCOLOGY 1260, 1260–61 (2020).

treatments in deciding whether to approve or block drugs.[179] These laws also shield insurers from absorbing the costs of the harms these treatments cause.[180] Right to Try and other erosions of FDA authority cannot be clawed back by targeting Part D patients with an obscure coverage rule.

The deregulatory/consumerist push is enabled by minimalist regulation of drug promotion. The U.S. is one of two countries where direct-to-consumer advertising of drugs is broadly legal, and drug companies direct even more resources to advertising drugs directly to medical professionals.[181] It is perhaps the righteous concern with advertising and promotion, most of all, that allows the Part D compendium restriction to appear related to the FDA's important regulatory responsibilities.[182] Americans are bombarded with drug ads; these ads sell them drugs as well as the idea that their fellow citizens are one Super Bowl ad away from bankrupting Medicare with their demands for a drug they saw on TV. But the absolute necessity of off-label *use* in everyday medicine cannot be confused with the dangers of the deregulated, free-market approach to off-label *advertising*.

Although courts have lent judicial imprimatur to an extremely restrictive interpretation of the compendium restriction, they have at the same time substantially eroded FDA efforts to regulate drug companies' direct marketing of off-label uses. Advertising FDA-approved drugs for off-label use was once flatly prohibited—and the FDA typically still usually takes the position that this is the case—but a series of federal court decisions have protected drug companies' advertising of off-label uses and shifted the burden to the FDA to initiate litigation to demonstrate such claims are false.[183] These erosions of FDA authority are most often justified on First Amendment

---

179. *See* Right to Try Act, Pub. L. No. 115-176, 132 Stat. 1374 (codified as amended at 21 U.S.C. § 360bbb).

180. Alison Bateman-House & Christopher T. Robertson, *The Federal Right to Try Act of 2017—A Wrong Turn for Access to Investigational Drugs and the Path Forward*, 178 JAMA INTERNAL MED. 321, 321 (2018).

181. Mehmet Yildiz, *Why the United States and New Zealand Are the Only Countries Allowing Drug Ads on TV*, MEDIUM (Nov. 10, 2024), https://medium.com/sensible-biohacking-transhumanism/why-the-united-states-and-new-zealand-are-the-only-countries-allowing-drug-ads-on-tv-1f37ef663113 [https://perma.cc/2PJA-X3YG]; Ana Swanson, *Big Pharmaceutical Companies Are Spending Far More on Marketing than Research*, WASH. POST (Feb. 11, 2015), https://www.washingtonpost.com/news/wonk/wp/2015/02/11/big-pharmaceutical-companies-are-spending-far-more-on-marketing-than-research [https://perma.cc/P66D-2PZK].

182. *See* Aaron, *supra* note 167, at 136 n.285 ("The court [in *Caronia*] reasoned that off-label *use* is legal, so 'it does not follow that prohibiting the truthful promotion of off-label drug usage by a particular class of speakers would directly further the government's goal[] of preserving the efficacy and integrity of the FDA's drug approval process.'") (emphasis and alterations in original).

183. *Id.* at 135–38.

grounds, with courts favoring a free market approach where the airwaves and print and social media are flooded with advertisements and people left to make individual determinations about whether companies' therapeutic claims are true or false.[184]

Patients are at once relied on to be competent consumers of all this information and treated as universally susceptible to demanding unnecessary treatments because of the influences of advertising. In this environment, public payers are seen as a backstop for these failures of industry-directed regulation, and their mission of facilitating utilization becomes secondary to their mission to root out assumed overutilization.[185] Combine this with the reputation of pharmaceutical companies as particularly ruthless in advertising and promotion, and it appears rational at first glance to apply burdensome scrutiny to claims for coverage of otherwise lightly regulated off-label uses in a public program.[186]

Erosion of and failures to exercise FDA authority in other areas make Part D payment rules seem like an available backdoor for asserting at least a modicum of authority over the market for off-label uses. Because Part D—via the plans it contracts with—is a prescription drug payer for tens of millions of people in the U.S., Part D beneficiaries are an appetizing market for drug companies. This is especially true because Part D also pays much higher prices for drugs than other public payors, also a deliberate and

---

184. *E.g.*, Amarin Pharma, Inc. v. U.S. Food & Drug Admin., 119 F. Supp. 3d 196, 226–29 (S.D.N.Y. 2015). Where the FDA has attempted to regulate or ban off-label uses of certain treatments and devices directly rather than through targeting advertising, courts have also invalidated such regulations on the grounds that they interfere with medical judgment and with the state-government domain of regulating the medical profession. *See also* Judge Rotenberg Educ. Ctr., Inc. v. U.S. Food & Drug Admin., 3 F.4th 390, 397 (D.C. Cir. 2021). In *Judge Rotenberg*, the D.C. Circuit struck down such a targeted regulation that appeared designed to ban a device that delivers electric shocks to the skin. *Id.* at 393. The device was frequently used at a private behavior modification facility credibly accused of using the treatment in torture of patients held there against their will. *Id.* Congress later amended the FDA statute to effectively overrule the D.C. Circuit's decision, but many people were subject to the treatment between the court decision and the amendment. *See* Consolidated Appropriations Act, 2023, Pub. L. No. 117-328, § 3305, 136 Stat. 4459 (2022).

185. *E.g.*, United States v. Caronia, 703 F.3d 149, 168 (2d Cir. 2012) (invalidating FDA restriction on off-label advertising on First Amendment grounds and suggesting instead that "[t]o minimize off-label use, or manufacturer evasion of the approval process for such use, the government could create other limits, including ceilings or caps on off-label prescriptions").

186. *See* Celine Castronuovo, *TikToker Drug Ads Spark Demands for FDA to Clarify Its Authority*, BLOOMBERG L. (Feb. 16, 2024), https://news.bloomberglaw.com/health-law-and-business/tiktoker-drug-ads-spark-demands-for-fda-to-clarify-its-authority. Of course, off-label uses *are* regulated through malpractice doctrine as well.

avoidable political choice.[187] But the exercise of *individual* coverage denials has no bearing on the FDA's mandate to ensure the safety and effectiveness of drugs for the population. It is also overinclusive, capturing off-label uses that are plainly safe and effective, and which even HHS has conceded are medically necessary for patients denied coverage.

The literature on off-label uses outside the specific Part D coverage context extensively discusses the lack of regulation of advertising and prescribing. Most scholars at least recognize off-label use will always be necessary, even if the current climate creates more risks than it should.[188] The FDA's mandate for drug approval requires ex ante evaluation of benefits and risks, with a preference for certain types of clinical trials and evidence that simply aren't possible to build for small patient groups or can't be conducted for ethical reasons. A stronger and more transparent premarket regulatory regime—which many agree is sorely needed—would probably slow the pace of certain drug approvals. This could be an acceptable outcome so long as using drugs off-label remains a possibility as post-approval information becomes available and clinicians can continue to rely on a variety of information in decision-making, especially when treating patients for whom an on-label approval is a remote possibility. Jeremiah's treatment was not experimental, dangerous, or frivolous, and he didn't learn about it on TV; it was the established standard of care and it worked, long before the compendia or the FDA recognized people like Jeremiah as worthy of treatment.

Safety, efficacy, and promotion of drugs are regulatory issues that require serious attention, but the compendium requirement is not the linchpin of the FDA's authority to regulate drugs. That the requirement continues to deny coverage for off-label uses that *are* safe, effective, and necessary shows it is undermining Part D coverage while not addressing any of the deep issues with drug regulation, promotion, and approval. Patients and their prescribers are at once capable of recognizing necessary off-label uses as well as the harms of dubious marketing, but Part D ignores this.[189] Furthermore, the compendium restriction affects only *payment*, not *use*, so the compendium

---

187. *See* CONG. BUDGET OFF., A COMPARISON OF BRAND-NAME DRUG PRICES AMONG SELECTED FEDERAL PROGRAMS 3–8 (2021).

188. *E.g.*, David A. Simon, *Off-Label Innovations*, 56 GA. L. REV. 701, 715 (2022).

189. Aaron S. Kesselheim et al., *Physicians' Perspectives on FDA Approval Standards and Off-Label Drug Marketing*, 179 JAMA INTERNAL MED. 707, 707–09 (2019) (In a survey of U.S. physicians, "[m]ost . . . thought that the FDA should 'definitely not' or 'probably not' allow off-label promotion to physicians and that it would be a 'bad idea' or 'terrible idea' to allow such promotion by sales representatives in physicians' offices . . . or in medical journals. . . . Physicians were much more likely to believe that off-label promotion would worsen (rather than improve) clinical decisions . . . ").

restriction merely serves to prevent patients who actually need their Part D coverage from using it, maintaining rather than closing yawning, income-based gaps in access to care.

B. Cost Containment and Manufactured Scarcity

Although the compendium restriction was never discussed in the legislative history as per se a cost-containment measure, its use to deny coverage of medically necessary prescription drugs still functions as, and is rationalized as, a necessary cost-containment measure. Such arguments in its favor appear fiscally sensible, yet they rely on a manufactured premise of scarcity and pursue cost-containment at the expense of individual care while doing nothing to address the inflated prices Medicare pays for prescription drugs.

1. The Specter of Overutilization and the False Promises of Privatization

In Medicare, cost-containment concerns arise from a mix of: (1) manufactured scarcity (e.g., of federal funding, through panic about the solvency of the Medicare Hospital Insurance/Supplemental Medical Insurance Trust Funds, despite the fund being wholly a creation of statute) and (2) in Part D specifically, the very real ballooning cost of prescription drugs. As one district judge opined, without evidence for the claim, the compendium restriction is "an essential feature of the Medicare Part D program—a coverage limitation that is central to the balance Congress struck between expanding prescription drug coverage and containing costs."[190] Concerns over public spending in general and drug costs in particular should be disentangled, to the extent possible, to examine the compendium requirement as a cost-saving measure.

The consumerism/economism approach toward regulation of drug information and promotion also positions patients as primarily responsible for program costs through their very utilization of healthcare. It has become axiomatic that, no matter how much Medicare costs, it costs too much, and that Medicare is under persistent threat of collapse unless such costs are

190. United States ex rel. Brown v. Celgene Corp., 226 F. Supp. 3d 1032, 1049 (C.D. Cal. 2016).

brought down.[191] Medicare's role as a healthcare payer specifically, and a social program generally, place it directly in the crosshairs of arguments against welfare spending and in favor of cost-containment as a central prerogative of redistributive government programs.[192]

Medicare's older and disabled beneficiaries are frequently painted as quite literally "responsible for" more than their fair share of healthcare costs.[193] These arguments against spending seek to rationalize utilization restrictions that are medically harmful and to justify the role of private interlopers who restrict access to care. Just as it offloads the costs of deregulation onto patients, the Part D compendium restriction also places outsized emphasis on patients' utilization of care—rather than on commodification of care, industry profit maximization, etc.—as a driver of costs.

Overutilization—a ubiquitous term in healthcare—is often used as a euphemism for what is merely high utilization, or obtaining healthcare not out of proportion to one's need but out of proportion with a hypothetical average person.[194] This term is relied on by private insurers to justify their position in the care economy. According to insurance principles, every patient is a potential "overutilizer," susceptible to malingering or claiming they need drugs and other treatments for a disease simply because they are influenced by trying on diseases like the latest fashion.[195] And their doctors may be viewed as sympathetically acquiescing because they have personal relationships with patients, whereas insurance company employees can

---

191. *See, e.g.*, Frank Pasquale, *The Hidden Costs of Health Care Cost-Cutting: Toward a Postneoliberal Health-Reform Agenda*, 77 L. & CONTEMP. PROBS. 171, 172 (2014); *see also* DAVID P. RICHARDSON, TIAA-CREF INST., TRENDS IN HEALTHCARE SPENDING AND HEALTH INSURANCE 1 (2008) ("Nearly two out of three dollars spent on retiree health care is financed by public programs. Continued solvency issues with the Medicare program imply that future retirees may face substantially larger health care financing risk."); James G. Chappel, *The Frozen Politics of Social Security*, BOSTON REV. (Feb. 13, 2023), https://www.bostonreview.net/articles/the-frozen-politics-of-social-security [https://perma.cc/NM4B-ZF8P].

192. Elenore Wade, *The Undeserving Poor and the Marketization of Medicaid*, 72 BUFF. L. REV. 875, 880–81 (2025).

193. *E.g.*, RICHARDSON, *supra* note 191, at 1 ("The elderly comprise 15 percent of the population but are responsible for 34 percent of health spending."); MEDICAID & CHIP PAYMENT & ACCESS COMM'N, MACSTATS: MEDICAID AND CHIP DATA BOOK 54 (2024) (showing that dually eligible enrollees were responsible for over $200 billion of Medicaid spending in fiscal year 2022); U.S. GOV'T ACCOUNTABILITY OFF., GAO-14-176, DEMOGRAPHICS AND SERVICE USAGE OF CERTAIN HIGH EXPENDITURE BENEFICIARIES 6–7 (2014); *see also* Marta Russell, *Eugenics and the "Sole Possible Economic Order"*, *in* CAPITALISM & DISABILITY 156–57 (Keith Rosenthal ed., 2019).

194. Charles P. Hall, Jr., *Deductibles in Health Insurance: An Evaluation*, 33 J. RISK & INS. 253, 255–56 (1966).

195. O. D. Dickerson, *The Problem of Overutilization in Health Insurance*, 26 J. INS. 65, 65–66 (1959).

review files and deny claims for unnecessary healthcare with a cold remove.[196] *Overutilization* as a vaguely defined bugbear is a useful term for those seeking to cast patients as responsible for a host of problems with U.S. healthcare; if you're not getting the healthcare you need—and in the U.S., there's a good chance you aren't—maybe it's because someone else is using too much.

Despite contemporary admissions by most commentators and politicians that Medicare is now part of the fabric of U.S. society, manufactured scarcity of public payment has served as a justification for proposals and enactments that scale back benefits and heighten eligibility requirements. Even ideological proponents of neoliberalization and privatization of Medicare still *claim* to be improving Medicare while they erode it by administrative means.[197] Medicare—like Social Security retirement benefits—is often discursively distinguished from welfare and poor people's programs like Medicaid because the people who receive their benefits have paid into the benefit system through taxes, premiums, and accumulation of work credits.[198] But attacks on these programs are still subject to anti-welfare tropes that paint social programs and their beneficiaries as burdens.[199] Despite the now-dominant view of Medicare as an earned benefit and a recognition of the merit of a society that cares for its elders, it was in the leadup to its enactment brutally castigated as a handout to the aged and disabled at the expense of moral injury to the young, healthy taxpayer.[200]

Social programs are singled out among government spending programs as costly to the public. *The public*, though, is deliberately circumscribed in these critiques, excluding direct beneficiaries of programs from the public who pays for them. Invectives against social spending are at their height when the identity of program beneficiaries is already one disqualified from the taxpayer/consumer identity—poor, disabled, racialized—and when the program allows for participant autonomy—for example, direct cash welfare

---

196. *Id.* at 66.

197.Christopher J. Niggle, *Globalization, Neoliberalism and the Attack on Social Security*, 61 REV. SOC. ECON. 51, 52–54 (2003); David A. Super, *The Political Economy of Entitlement*, 104 COLUM. L. REV. 633, 643–44 (2004).

198. *See* Alan G. Nasser, *"Saving" Social Security: A Neoliberal Recapitulation of Primitive Accumulation*, 52 MONTHLY REV. 42, 42 (2000) (reviewing DEAN BAKER & MARK WEISBROT, SOCIAL SECURITY: THE PHONY CRISIS (2001)); Super, *supra* note 197, at 646.

199. *E.g.*, David Lerman, *Conservatives' Budget Plan Renews Battle over Seniors' Benefits*, ROLL CALL (June 14, 2023), https://rollcall.com/2023/06/14/conservatives-budget-plan-renews-battle-over-seniors-benefits [https://perma.cc/69H8-SD9M].

200. *Testimony of the American Medical Association*, *in* 2 STATUTORY HISTORY OF THE UNITED STATES: INCOME SECURITY 728 (Robert B. Stephens ed. 1970); *see also* Niggle, *supra* note 197, at 54–56.

and traditional Medicare. But such invectives tend to fade into the background, even if public spending will remain stable or increase, when the spending will accomplish upward redistribution while restricting the autonomy of those who benefit from a program's downward redistribution.[201]

Controlling costs in social programs is seen as a goal in and of itself even if cost-containment measures would undermine the programs' primary purpose of paying for healthcare as a means to promote health and well-being. For example, although receipt of Social Security Disability Insurance (SSDI) beneficiaries confers automatic eligibility for Medicare, the federal government has imposed, since 1972, an arbitrary two-year waiting period between SSDI eligibility and the receipt of Medicare.[202] Congress justified this as a cost-containment measure and a way to avoid competing with private insurance plans.[203] The measure surely contains costs in the short term, but people die or get sicker because of it. A public program cannot succeed if it views cost-containment, regardless of how it is accomplished, as a mandate that supersedes the care mandate.[204] Although the Part D compendium restriction was never directly justified in the legislative history as a cost-containment measure, the restriction and other utilization control measures are readily accepted by courts and economists as necessary to public healthcare payment schemes even where they are harmful to patients.[205]

The privatization trend that reached its apex in Medicare Part D relied on portrayals of private industry as efficient and of government payers as a costly bureaucracy that undermined the "voluntary relationship existing between a patient and his doctor" by "supplanting the individual as the purchaser of healthcare."[206] Part D was a cornerstone of George W. Bush's "Ownership Society," the "conceptual battering ram" with which the administration and its industry partners sought to "persuade Main Street America that privatizing Social Security is a viable and, indeed, desirable

---

201. *See, e.g.*, Zohra Ahmed, *The Right to Counsel in a Neoliberal Age*, 69 UCLA L. REV. 442, 479–81 (2022).

202. CONG. RSCH. SERV., RS22195, SOCIAL SECURITY DISABILITY INSURANCE (SSDI) AND MEDICARE: THE 24 MONTH WAITING PERIOD FOR SSDI BENEFICIARIES UNDER AGE 65 3 (2009).

203. James Lubitz & Penelope Pine, *Health Care Use by Medicare's Disabled Enrollees*, 7 HEALTH CARE FIN. REV. 19, 29 (1986).

204. The neglect of the care mandate leads governments down some bizarre, if less directly harmful, paths. For example, Arizona's state Medicaid agency is now called the "Arizona Health Care Cost Containment System," or AHCCCS, pronounced *access*.

205. *See generally* Gary V. Engelhardt & Jonathan Gruber, *Medicare Part D and the Financial Protection of the Elderly*, 3 AM. ECON. J.: ECON. POL'Y 77 (Nov. 2011) (reflecting economists' acceptance of Part D as a redistributive policy).

206. *Statement of American Medical Association*, *supra* note 200, at 728.

strategy."[207] Through these statements, Part D's structure is legible as a fruit of what Ruth Wilson Gilmore calls the anti-state state—anti-state actors gain and wield state power against social programs while at the same time denouncing state power and collective social responsibility.[208] This rejection of interdependency facilitates the systematized abandonment of people painted as dependent on government.[209] The Cato Institute touted Medicare privatization and the Ownership Society as a way for "patients [to] control their own healthcare" by "freeing them from dependence on government handouts and making them owners instead."[210]

Of course, government would not be getting out of the business of healthcare at all; Part D—one of the Ownership Society's signature achievements—was plainly a colossal new government spending program. But instead of a program defined exclusively as a social good, Part D would assist in transforming the federal government into a vehicle for swift upward redistribution, transmitting massive sums of public money away from direct assistance and toward private firms. In doing so, it restricted enrollees' autonomy by subjecting drug coverage to private insurance rationing, placing intermediaries between patients and payments. Furthermore, it stripped the public of political autonomy by diffusing care decisions across an array of private actors rather than leaving room for the public to influence the distribution of Medicare benefits.

The private-plan model encourages beneficiaries of social programs to adopt consumer identities by forcing them to sift through dozens of private plans, and it uses plan sponsor intermediaries to influence patients to "confront financial incentives to economize on health care."[211] That is, just as with the consumerist approach to FDA regulation discussed above, such programs achieve cost-containment by imposing restrictions at the individual level, replicating in public programs the same market phenomenon that public programs should intend to upset rather than reproduce—the provision of medical care based on ability to pay rather than need.

Privatization costs the public in fiscal and social terms. For example, since the inception of Medicare Advantage—a private alternative to traditional Medicare Parts A and B—it has consistently cost the federal government

---

207. Susanne Soederberg, *Freedom, Ownership, and Social (In-)Security in the United States*, 65 CULTURAL CRITIQUE 92, 92 (2007).

208. RUTH WILSON GILMORE, ABOLITION GEOGRAPHY: ESSAYS TOWARDS LIBERATION 34 (Brenna Bhandar & Alberto Toscano eds., 2022).

209. *Id.*

210. Soederberg, *supra* note 207, at 92–93.

211. Jonathan Oberlander, *The Political Economy of Unfairness in U.S. Health Policy*, 69 L. & CONTEMP. PROBS. 245, 259 (2006).

billions more than traditional Medicare.[212] This is despite Medicare Advantage plans' well-documented propensity for disenrollment, selection of enrollees who will use less medical care, and tendency to force the attrition of MA enrollees back to traditional Medicare when they need more care.[213] Even after the Affordable Care Act imposed some controls on "overpayments" to Medicare Advantage plans, the federal government has estimated it will spend $88 billion more on Medicare Advantage than on traditional Medicare in 2024.[214] CMS also repeatedly finds "widespread and persistent problems" when it audits Medicare Advantage and Part D contractors claims reviews, and "[d]espite CMS efforts to educate [plans] about persistent problems in Medicare Advantage, each year during its audits of different [plans], CMS finds many of the same violations as in previous years."[215] Instead of credulously insisting these issues are a bug, it is long past time to recognize they are a feature of privatization of public programs.

That privately controlled Medicare Advantage and Part D programs cost more than public programs without any improvements in care quality was entirely predictable. It is true that private entities are more aggressive than public entities in their utilization controls and put up more barriers to care[216]—this is the basis for claims that privatization reduces costs. But these avoided costs redound to the benefit of the medical insurance and pharmacy benefit companies that receive MA and Part D subsidies from the public. In their representations to shareholders, these companies tout the country's aging population and the growth of their Medicare businesses as reliable drivers of ever-increasing enrollment and profit. Medicare is the medical insurance industry's "golden goose" and Medicare Advantage "can be twice as profitable for insurers than other types of plans."[217] As Andrew S. Kelly has put it,

> [T]he insurance industry gained a new type of power over the direction of health care reform. This new power is used to preserve a delegated form of public insurance not because this piece of the

---

212. Rebecca Pifer, *MA Spending to Outstrip Traditional Medicare by $88B This Year*, MEDPAC, (Jan. 16, 2024), https://www.healthcaredive.com/news/medicare-advantage-overpayments-medpac-2024/704579 [https://perma.cc/DT6D-2ZBH].

213. *See* David J. Meyers et al., *Analysis of Drivers of Disenrollment and Plan Switching Among Medicare Advantage Beneficiaries*, 179 JAMA INTERNAL MED. 524, 525–27 (2019).

214. Pifer, *supra* note 212.

215. U.S. DEPT. OF HEALTH & HUM. SERVS., *supra* note 97.

216. Eva Goetjes & Katharina E. Blankart, *Insurance Barriers and Inequalities in Health Care Access: Evidence from Dual Practice*, HEALTH ECON. REV. (Mar. 21, 2024), https://healtheconomicsreview.biomedcentral.com/articles/10.1186/s13561-024-00500-y [https://perma.cc/8KHE-9X6B].

217. Pifer, *supra* note 212.

> welfare state supports the goals of business, but because Medicare and Medicaid have *become* the business of the insurance industry.[218]

In addition to removing the private rent-seeking that consumes Medicare spending without playing a direct role in care delivery, another solution to manufactured payment scarcity in Medicare would be to simply end the artificial cap on Medicare spending. The current structure of Medicare, particularly the fear-driven panic over the solvency of the Medicare Trust Funds, often serves as a justification for cost-cutting measures and the privatization of care.[219] This manufactured scarcity—where funding limits are framed as a near-term crisis—creates an environment where cost-containment becomes the central goal, even at the expense of patient care. By removing these artificial caps and ensuring a steady, adequate stream of funding, Medicare could focus on its core mission: providing comprehensive healthcare to those in need without the constraints imposed by arbitrary fiscal limits. This would allow for expanded coverage, greater benefits, and a re-emphasis on patient needs rather than market-driven priorities. An essential part of ensuring Medicare's sustainability and effectiveness is utilizing taxation more equitably to fully fund the program.

Claims that cost-containment is a central goal of Medicare are undermined by the very structure used to administer pharmacy benefits: subsidized private plans that pay private pharmacy benefit managers (PBMs) to pay pharmacies and negotiate rates.[220] While the rhetoric of cost-containment suggests a

---

218. Andrew S. Kelly, *Private Power in Public Programs: Medicare, Medicaid, and the Structural Power of Private Insurance*, 37 STUD. AM. POL. DEV. 24, 25 (2023); *see also* Susan Morse, *Big 5 Insurers Depend on Medicare, Medicaid for Growth in Enrollment, Profit* (Dec. 5, 2017), https://www.healthcarefinancenews.com/news/big-5-insurers-depend-medicare-medicaid-growth-enrollment-profits ("UnitedHealthcare, Anthem, Aetna, Cigna, and Humana collectively cover 43 percent of the total U.S. insured population, the report said. Due in large part to an aging baby boomer population, Medicare and Medicaid account for nearly 60 percent of the big five's revenues and 20 percent of their plan membership.").

219. *See, e.g.*, Romina Boccia & Dominik Lett, *Economic Growth Won't Save Social Security: New Paper Release*, CATO INST. (Feb. 12, 2025), https://www.cato.org/blog/economic-growth-wont-save-social-security-new-paper-release [https://perma.cc/E7KA-TZ2Y]; Fatima Hussein, *Social Security Has Existed for 90 years. Why It May Be More Threatened Than Ever*, 6ABC (Aug. 14, 2025), https://6abc.com/post/social-security-has-existed-90-years-may-more-threatened/17535360/#:~:text=Some%20call%20for%20shrinking%20the,All%20Rights%20Reserved [https://perma.cc/4Z35-HX66]; Scott Horsley, *Social Security Benefits Face Big Cuts in 2033, Unless Congress Acts*, NPR (June 18, 2025), https://www.npr.org/2025/06/18/nx-s1-5436828/social-security-benefits-cut-congress [https://perma.cc/29TA-S73E].

220. CONG. RSCH. SERV., R40611, MEDICARE PART D PRESCRIPTION DRUG BENEFIT 57, 57 n. 203 (2023) ("A 2019 Government Accountability Office (GAO) study found that PBMs

desire to reduce spending, the involvement of private insurers and PBMs, which act as intermediaries between the government, insurers, and pharmaceutical companies, often leads to the opposite outcome. PBMs extract significant profits by negotiating rebates with drug manufacturers, but these rebates do not necessarily translate into lower prices for consumers. Beyond the excess costs of using private plans in the first place, these intermediaries often engage in practices that drive up costs for both patients and the public system.

2. Addressing Drug Costs Directly

Beyond the privatized model, the Part D program also built in another guarantee of high costs. Consistent with the negative portrayal of the bureaucracy that sustains social programs, the Part D law also barred the federal government from directly negotiating the drug prices paid by the new program pursuant to a provision that mandates government noninterference with plans' individual negotiations with drug manufacturers.[221] In a hearing on the Part D bill, under questioning about this noninterference provision, HHS Secretary Tommy Thompson explained that "PBMs or PPOs or HMOs that are going to be negotiating directly with pharmaceutical companies . . . could do a much better job than the bureaucrats in HHS or me as secretary."[222]

Of course, claims that "the bureaucrats in HHS" would get worse deals than private plans turned out to be plainly untrue. Noninterference has denied the federal government its bargaining power over drug prices, resulting in Medicare paying far more for drugs than Medicaid and the VA.[223] Despite Part D being a clear expansion of coverage on the one hand, members of Congress and the public were wise to the aims of the new drug prescription drug program and its medical insurance counterpart, Medicare Advantage. Patients would not have more control over their own destinies, but less, because a different kind of bureaucrat was entering the fray, and this kind of bureaucrat would have all the wrong incentives when it came to providing

---

performed 74% of drug benefit management services for Part D plans. . . .Some large Part D sponsors own their own PBMs, including CVS Caremark, UnitedHealth Group, and a coalition of Blue Cross/Blue Shield plans. Other sponsors may contract with outside PBMs for services.").

221. 42 U.S.C § 1395w-111(i).

222. *Department of Health and Human Services Fiscal Year 2005 Budget Request: Hearing Before the H. Comm. On the Budget*, 108th Cong. (2004) (statement of Tommy Thompson, Secretary of Health & Human Services).

223. Elenore Wade, *Health Injustice in the Laboratories of Democracy*, 29 GEO. J. ON POVERTY L. & POL'Y 177, 212 (2022).

care. Summarizing an editorial published in the *Des Moines Register*, Massachusetts Senator Ted Kennedy said of the bill:

> This bill does virtually nothing regarding costs. . . . This conference report represents a right-wing agenda to privatize Medicare and force senior citizens into HMOs and private insurance plans. I guess seniors should not get to choose their doctor and hospital, they just do not know enough. That choice should be made for them by the insurance company bureaucrats. The conference report includes no serious program to reduce the double-digit drug price increase.[224]

In public polling, a majority of people who said they had closely followed the debate over prescription drug coverage legislation said they disapproved of the program as enacted, and commentators lamented that "the group that should have come out on top—America's seniors—was reeling and confused at the prospect of limited help, while watching industry groups count their booty."[225] Patients are drivers of program costs in the sense that utilization of healthcare does indeed cost money; if no one used Medicare, it would not cost anything. But the drivers of Medicare's *outsized* costs are due to systemic features of the program. The latter drivers are avoidable, but rather than avoiding them, Part D applies undue scrutiny to individual utilization in order to pursue meager cost savings at the expense of patient care. Only recently, pursuant to the Inflation Reduction Act of 2022,[226] has Congress granted Medicare authority over direct negotiations with manufacturers. However, the first round of negotiations included only ten drugs, so its effects on the program as a whole are yet to be seen.[227]

The compendium restriction—which offers the most durable claims-rejection method available to Part D plans—represents an extremely unfriendly convergence of Part D's various flaws. Every rejected claim has

---

224. 149 CONG. REC. 15140 (2003) (statement of Sen. Edward M. Kennedy). This aspect of private administration of Medicare Advantage and Part D has led one scholar to conclude administration of public healthcare payment programs by private managed care organizations is simply so irreconcilable with Due Process that it is unconstitutional. *See* Jennifer L. Wright, *Unconstitutional or Impossible: The Irreconcilable Gap Between Managed Care and Due Process in Medicaid and Medicare*, 17 J. CONTEMP. HEALTH L. & POL'Y 135, 135–39 (2000).

225. Thomas R. Oliver et al., *A Political History of Medicare and Prescription Drug Coverage*, 82 MILBANK Q. 283, 284–85 (2004).

226. Inflation Reduction Act of 2022, Pub. L. No. 117–169, 136 Stat. 1818 (2022).

227. Tami Luhby, *Drugmaker Industry Group Sues to Stop Medicare Drug Price Negotiation*, CNN (June 21, 2023), https://www.cnn.com/2023/06/21/politics/medicare-drug-price-negotiation-lawsuit-phrma#:~:text=The%20agency%20will%20send%20an,%25%20of%20sales%2C%20PhRMA%20argues [https://perma.cc/4ZSQ-27ZL].

the potential to harm an individual patient—jeopardizing care and leading to household debt and deprivation—but even the tens of thousands of claims rejected annually on compendium grounds cannot be seriously said to promote any legitimate cost-savings goal of Medicare, through which more than fifty million people have prescription drug coverage.[228] Instead, high costs are a *feature* of the program's upward redistribution and private administration. Failure of government to intercede at the industry level and a misdirected, excessive focus on healthcare utilization by individuals begins to make Medicare act like a program whose primary goal is to reduce healthcare utilization rather than to enable it.

Even if fiscal scarcity in the Medicare program is manufactured, it is unquestionably true that drugs in the United States are very, very expensive. One can defend social spending without accepting these costs. The U.S. is a strange drug market, with its ubiquitous direct-to-consumer drug advertising, high prices for pharmaceutical products, relative industry consolidation at both the manufacturing and benefit levels,[229] and a patent regime extraordinarily weighted toward producing benefits for industry giants at the expense of production of cheaper and more widely available medicines.[230] Combine this with Medicare Part D, itself a monumental concession to the pharmaceutical manufacturing and pharmacy benefits industries, and it is unjustified but perhaps unsurprising that any cost-savings ultimately come at the expense of patient care instead of those subsidized industries.

To the extent that Part D has a cost-control mandate at all, it is functionally incapable of achieving it by design because it replaces a payor-regulator role for government with an insurer-business partner role. Cost-savings at patient expense are the worst of both worlds. They routinely hurt individual patients while being unable to effect any kind of meaningful system-wide costs savings. In this "paradox of excess and deprivation," patients suffer while the

---

228. *Medicare Monthly Enrollment,* CTRS. MEDICARE & MEDICAID SERVS. (July 21, 2025), https://data.cms.gov/summary-statistics-on-beneficiary-enrollment/medicare-and-medicaid-reports/medicare-monthly-enrollment [https://perma.cc/3D5X-ZAT7].

229. Elizabeth Seeley & Surya Singh, *Competition, Consolidation, and Evolution in the Pharmacy Market*, THE COMMONWEALTH FUND (Aug. 12, 2021), https://www.commonwealthfund.org/publications/issue-briefs/2021/aug/competition-consolidation-evolution-pharmacy-market [https://perma.cc/C3NA-FLHB].

230. Veronica Salib, *Comparing Global Pharmaceutical Markets: US, UK, and China*, TECHTARGET (Feb. 7, 2023), https://pharmanewsintel.com/features/comparing-global-pharmaceutical-markets-the-us-uk-and-china [https://perma.cc/X33H-GQ9J]; Bob Herman, *The U.S. Is the Drug Industry's Gold Mine*, AXIOS (Sept. 30, 2021), https://www.axios.com/2021/09/30/drug-prices-pharma-revenue-usa-international [https://perma.cc/69C6-3U3S].

healthcare and insurance industries thrive.[231] There are many ways to reduce the costs of the Medicare program in general and Part D in particular without the use of a provision that disproportionately targets disabled patients to deny them coverage. The cost-savings argument in favor of the compendium requirement falls short if for no other reason than that Part D is the only program that contains this unique restriction on drug coverage, yet it still spends far more on drugs than other public payers that have no such restriction.

IV. CONCLUSION: WHY HEALTH JUSTICE DEMANDS REPEAL OF THE COMPENDIUM RESTRICTION

Medicare Part D cannot serve its purpose while the compendium restriction exists. As discussed in Part II, procedural tweaks and increased fairness or access in administrative appeals won't save the restriction. So long as it remains law, it is a special coverage restriction without reason or justification, undercutting the general rule that public programs must pay for necessary care. Post hoc rationales—regulation and cost-savings—do nothing to salvage it. Somehow absent in the discussion of these post hoc rationales is the very basic premise of the Medicare program, which is that the government and the public have an interest in promoting the welfare of the population rather than just the interests conveniently projected onto them, such as illusory cost-savings, at any cost.

A health justice framework calls for the design and evaluation of healthcare financing laws to be rooted in the public interest in promoting health and attacking disparate vulnerability to illness and death. Especially in a program with the primary purpose of enabling care through payment, this entails assessing whether the law promotes or hinders access to care, and the compendium restriction quite obviously does hinder access.

Furthermore, a health justice framework also emphasizes the importance of democratic accountability and popular participation in policy formation. Medical ethicists discuss how one aspect of participation—localized, individualized informed consent—involves "two rights: the negative right to say no to a treatment and the positive right to participate in medical decision-making."[232] But questions about political autonomy go beyond these

---

231. Oberlander, *supra* note 211, at 251 (quoting THOMAS S. BODEHEIMER & KEVIN GRUMBACH, UNDERSTANDING HEALTH POLICY: A CLINICAL APPROACH 1 (4th ed. 2005)).

232. S. M. R. Lauridsen et al., *The Secret Art of Managing Healthcare Expenses: Investigating Implicit Rationing and Autonomy in Public Healthcare Systems*, 33 J. MED. ETHICS 704, 705 (2007).

questions of individualized distribution to the very heart of another right: the right of the people to play a meaningful role in distributing Medicare's benefits rather than just passively receiving them when they become eligible. Unlike localized questions about informed consent, the compendium restriction is a form of global rationing, carried out in this case by the federal government, which "governs the distribution of goods of a system at large . . . ."[233] This kind of rationing affects both individual and political autonomy because it relies on obscure, hidden rules over which the public has had no meaningful control or even access.

The Part D program is ripe for change and reimagination. Although eliminating the compendium restriction is just one part of such a reimagination, it will have immediate benefits for Part D enrollees and is a small step in pursuit of health justice. Because of its exclusivity to Medicare, the restriction's burdens fall on older and disabled people, and the patients most likely to be harmed by it are those with rare diseases. Although the conversation around rare diseases often revolves around discovery and production of treatments where none are available, the problems caused by the compendium restriction demonstrate that no fruit of innovation will ever be equally distributed so long as care is tied to ability to pay rather than need. The compendium restriction denies payment for treatments that *are* available solely because patients have rare diseases that may never obtain explicit mention in one of the two Medicare compendia. This means disabled Part D enrollees may be denied treatment for the very conditions that led to eligibility for Medicare in the first place, and this conflict cannot be reconciled or justified. Part D works directly against the economic and disability justice otherwise promoted by public payment for healthcare when it excludes all available treatments for certain medical conditions, effectively blacklisting certain people from the program and deeming them unworthy of social care.

Furthermore, pursuant to the transfer of Medicare-Medicaid dual eligibles into Part D upon its enactment, the compendium restriction also ensnares tens of millions of poor and low-income people, raising serious economic justice issues. Beyond this, because plans are so quick to use the restriction as grounds for denial, even erroneously, the restriction captures even more patients who could ostensibly prove coverage but don't have the resources to pursue four stages of Medicare appeals and judicial review.

Furthermore, wholesale repeal of the compendium restriction is necessary not only because individual pursuit of Medicare appeals and judicial review

---

233. *Id.*

is practically impossible for many people, but also because reforming federal healthcare payment cannot continue to depend on disease-based carveouts like the 2008 addition of a compendium carveout for anti-cancer chemotherapy drugs. These carveouts don't threaten the broader coverage restrictions that necessitate carveouts in the first place; in fact, they may ossify them. Instead of politically marginalizing the restrictions themselves, carveouts politically marginalize the patients who don't benefit from carveouts. Just as the federal government reduces its own bargaining power through program-specific and plan-based drug pricing negotiations, the public reduces its bargaining power over the future of Medicare and public payment for healthcare with fragmented, disease-based advocacy. For example, the addition of disease-specific carveouts—such as in the exceptions to the two-year Medicare waiting period for SSDI recipients and the recently implemented cap on insulin costs for Medicare beneficiaries—placates the most organized patient groups and creates the appearance that carveouts are resolving problems within programs. These exceptions make calls for change seem less and less urgent.

Part D is practically in its infancy—it is fewer than two decades old—and should be recognized as such. There is no reason to treat its current structure as a settled issue, especially because the very same issues it claimed to address persist. In fact, the program could have been much worse. At first, the Bush Administration and its Ownership Society brethren imagined a new federal drug coverage program that would eliminate traditional Medicare altogether. These original proposals would have made drug coverage available only to beneficiaries who bought Medicare Advantage plans and disenrolled in traditional Medicare. But although Part D could have been worse, it could also be much better. Part D experimented with ceding governance of a social program almost entirely to private entities with an unreliable Medicare appeals process and the remote prospect of judicial review as the only way to address these failures of governance. The compendium language—even if once intended as an enlargement of coverage—has, in Part D, encouraged and enabled those entities to interfere substantially with public healthcare payment and given their excessive utilization controls the full backing of the state.[234]

Medicare enrollees do not have to be a pass-through or collateral entity for transactions in which the federal government gives billions of dollars to a few private companies. The federal government and the public have an interest in

---

234. *See* Stephanie Masaba, Note, *Diagnosed with Time Is Money: Arbitrary Medicare Provisions Differentiating Observation Services from Inpatient Admissions Violate Beneficiaries' Due Process Rights*, 23 WM. & MARY BILL RTS. J. 1185, 1206–07 (2015).

the Part D program doing what Congress claimed it set out do: spend public funds to promote health and welfare and end a state of affairs where patients' only choices were to forgo care or go into debt to pay for prescription drugs. This state of affairs is exactly what the compendium restriction maintains.

Medical assistance programs like the VA's integrated health system and Medicaid have done a much better job of addressing this problem and Part D's off-label coverage rules should, at the very least, be aligned with those of other public programs. Truly achieving these goals requires drastic change—for example, recognition that the privatization experiment has concluded and wrapping drug coverage into traditional Medicare and, beyond that, far more sweeping changes—but eliminating the compendium requirement would have immediate effects by removing an easily available avenue for private plans to pursue their worst excesses at the expense of patients.