

More Prices, More Problems: Challenging Indication-Specific Pricing as a Solution to Prescription Drug Spending in the United States

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ABSTRACT

In the United States, high prices of prescription drugs and rapidly increasing prescription drug spending have caused public outrage and calls for action. There is bipartisan acknowledgement of the problem by lawmakers, but no agreement on how to fix it. Value-based pricing models have gained increasing support and have been suggested as one possible solution to controlling prescription drug spending. One proposed value-based pricing model is indication-specific pricing: linking the price of a multi-indication prescription drug with the indication for which it is prescribed to a patient. Indication-specific pricing is intended to incentivize using higher-value treatments and allocating prescription drugs to patients who will receive the greatest benefit. However, there are many barriers to implementing indication-specific pricing in federal health insurance programs in the United States. Further, as a policy matter, indication-specific pricing would likely not decrease overall prescription drug spending and could worsen the accessibility and affordability of prescription drugs. This Note argues that lawmakers should not pursue an indication-specific pricing regime as a means to decrease prescription drug spending. Instead, lawmakers seeking prescription drug reform should consider methods that will more likely decrease prescription drug prices and spending while also ensuring patients' access to medicines.

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INTRODUCTION

The high cost of prescription drugs is a matter of serious concern in the United States. Several drug pricing scandals have elicited public outrage.¹ Gilead Sciences priced a twelve-week course of treatment for its first two hepatitis C treatments, Sovaldi and Harvoni, at \$84,000 and \$94,500 respectively.² Turing Pharmaceuticals raised the price of Daraprim, a treatment for toxoplasmosis, by 5,000 percent, from \$13.50 to \$750 per pill, immediately after acquiring rights to the drug.³ Many new cancer drugs have been released and priced at hundreds of thousands of dollars per year.⁴ Amgen's cancer drug Blincyto was approved in 2014 at a price of \$178,000⁵ and Novartis' cancer treatment Kymriah was approved in 2017 at a price of \$475,000.⁶ The average cancer drug now costs four times the average household income.⁷ Unaffordable prescription drugs can lead to patient non-adherence, worsening health outcomes and increasing use and cost of

1. See, e.g., Peter J. Neumann & Joshua T. Cohen, *Measuring the Value of Prescription Drugs*, 373 NEW ENG. J. MED. 2595, 2595 (2015) (“Escalating drug prices have alarmed physicians and the American public and led to calls for government price controls.”); Charles Ornstein & Katie Thomas, *Prescription Drugs May Cost More With Insurance Than Without It*, N.Y. TIMES (Dec. 9, 2017), <https://www.nytimes.com/2017/12/09/health/drug-prices-generics-insurance.html> (describing the current time period as “an era when drug prices have ignited public outrage and insurers are requiring consumers to shoulder more of the costs”); Andrew Pollack, *High Cost of Sovaldi Hepatitis C Drug Prompts a Call to Void Its Patents*, N.Y. TIMES (May 19, 2015), <https://www.nytimes.com/2015/05/20/business/high-cost-of-hepatitis-c-drug-prompts-a-call-to-void-its-patents.html> (on Sovaldi scandal) [hereinafter Pollack, *High Cost*]; Andrew Pollack, *Drug Goes From \$13.50 a Tablet to \$750, Overnight*, N.Y. TIMES (Sept. 20, 2015), <https://www.nytimes.com/2015/09/21/business/a-huge-overnight-increase-in-a-drugs-price-raises-protests.html> (on Daraprim scandal) [hereinafter Pollack, *\$750 Overnight*].

2. See; Carolyn Y. Johnson & Brady Dennis, *How an \$84,000 drug got its price: 'Let's hold our position ... whatever the headlines'*, WASH. POST (Dec. 1, 2015), https://www.washingtonpost.com/news/wonk/wp/2015/12/01/how-an-84000-drug-got-its-price-lets-hold-our-position-whatever-the-headlines/?utm_term=.68eea7c17de8.

3. See Pollack, *\$750 Overnight*, *supra* note 1.

4. See SUSAN DENTZER & TOM HUBBARD, VALUE-BASED CONTRACTING FOR ONCOLOGY DRUGS: A NEHI WHITE PAPER 10, 11 (2017) (discussing Keytruda, a \$150,000 per year treatment for metastatic melanoma, and Kymriah, a \$475,000 personalized treatment for pediatric and adult patients with a type of acute lymphoblastic leukemia); Emily K. White, *Killing U.S. Slowly: Curing the Epidemic Rise of Cancer Drug Prices*, 72 FOOD AND DRUG L. J. 189, 191 (2017) (“Over the past fifteen years, the average price of a cancer drug has increased ten to fifteen times, costing patients over \$100,000 a year in 2012.”).

5. See White, *supra* note 4, at 191.

6. See Denise Grady, *F.D.A. Approves First Gene-Altering Leukemia Treatment, Costing \$475,000*, N.Y. TIMES (Aug. 30, 2017), <https://www.nytimes.com/2017/08/30/health/gene-therapy-cancer.html>.

7. Julia Belluz, *The Nobel Prize is a reminder of the outrageous cost of curing cancer*, VOX (Oct. 2, 2018), <https://www.vox.com/science-and-health/2018/10/1/17923720/immunotherapy-cancer-cost>.

other health services.⁸

The problem of high prescription drug prices goes far beyond these few surprising examples. On average the United States spends twice as much as other countries on prescription drugs.⁹ Prescription drug spending accounted for approximately 17 percent of all healthcare spending in 2015 and is the fastest growing portion of the healthcare budget.¹⁰ Total prescription drug spending in the United States rose 12 percent in 2015 and another 6 percent in 2016, reaching \$450 billion.¹¹ These high and increasing prices are a result of several factors, including the higher prices paid for prescription drugs under patent compared to generics, weaker negotiating power of federal government payers, and rapid adoption of newly released prescription drugs in the United States.¹²

When polled in 2015, the public expressed that its top health policy priority

8. See White, *supra* note 4, at 190 (explaining the strategic choices of the pharmaceutical industry “have also left many Americans unable to afford their medications; particularly patients who are elderly, socioeconomically disadvantaged, or suffer from chronic diseases.”); Steven G. Morgan & Augustine Lee, *Cost-related non-adherence to prescribed medicines among older adults: a cross-sectional analysis of a survey in 11 developed countries*, *BMJ OPEN* 1, 1 (2017); Peter B. Bach & Steven D. Pearson, *Payer and Policy Maker Steps to Support Value-Based Pricing for Drugs*, 314 *J. AM. MED. ASS’N* 2503, 2503 (2015); Aurel O. Iuga & Maura J. McGuire, *Adherence and health care costs*, 7 *RISK MGMT. AND HEALTHCARE POL’Y* 35, 37 (2014) (“Between \$100 and \$300 billion of avoidable health care costs have been attributed to nonadherence in the US annually, representing 3% to 10% of total US health care costs.”).

9. See Margot Sanger-Katz, *Prescription Drug Costs Are Rising as a Campaign Issue*, *THE UPSHOT* (Sept. 21, 2015), <https://www.nytimes.com/2015/09/22/upshot/prescription-drug-costs-are-rising-as-a-campaign-issue.html>. See also DAVID O. SARNAK ET AL., *PAYING FOR PRESCRIPTION DRUGS AROUND THE WORLD: WHY IS THE U.S. AN OUTLIER?* 2 (2017). Interestingly, this is not the case for generic drugs, which are cheaper in the United States. See Tal Gross & Miriam J. Laugesen, *The Price of Health Care: Is the United States an Outlier?*, 42 *J. HEALTH POLITICS, POL’Y & L.* 771, 774 (2018). Humira, which costs on average \$2,669 for a 28-day supply in the United States, costs just \$1,362 in the United Kingdom and \$822 in Switzerland. THE PEW CHARITABLE TRUSTS, *PAYMENT POLICIES TO MANAGE PHARMACEUTICAL COSTS: INSIGHTS FROM OTHER COUNTRIES* 9 (Mar. 2017). Similarly, Harvoni, which costs on average \$32,114 for a 28-day supply, costs \$22,554 in the United Kingdom and \$16,861 in Switzerland. *Id.*

10. AARON BERMAN ET AL., *CURBING UNFAIR DRUG PRICES: A PRIMER FOR STATES* 4 (Aug. 2017). In 2014, after a period of relatively stable drug spending, prescription drug spending in the United States increased by 12 percent when adjusted for inflation. See Sanger-Katz, *supra* note 10.

11. Aaron S. Kesselheim, *Health Law Year in P/Review: Prescription Drug Prices* (Dec. 12, 2017), <https://vimeo.com/247814795#t=27m14s>.

12. THE PEW CHARITABLE TRUSTS, *supra* note 9, at 9-10; Aaron S. Kesselheim et al., *The High Cost of Prescription Drugs in the United States: Origins and Prospects for Reform*, 316 *J. AM. MED. ASS’N* 858, 860 (2016) (“Drug prices are higher in the United States than in the rest of the industrialized world because, unlike that in nearly every other advanced nation, the US health care system allows manufacturers to set their own price for a given product.”). New prescription drugs often enter the market at extremely high prices: the average price of a new drug or biologic in 2016 was over \$17,000 per month. See EXPRESS SCRIPTS, *PRESCRIPTION DRUG PRICING: A PUBLIC POLICY ANALYSIS* 5 (Feb. 2017).

was making prescription drugs more affordable.¹³ Since then, politicians from both sides of the aisle have called for prescription drug pricing reform.¹⁴ President Trump has asserted that he and Secretary of Health and Human Services Azar will decrease the price of prescription drugs.¹⁵ Since then, the Trump Administration has made various proposals to combat high prescription drug prices. In his first proposal, President Trump focused on the high list prices, the lack of negotiating tools, high out-of-pocket costs, and the lower prices for drugs in other countries.¹⁶ Another proposal suggested decreasing prescription drug prices and spending under Medicare Part B by changing the way physicians pay for and are reimbursed for drugs.¹⁷

The federal government has shown interest in exploring value-based payment

13. Erin Trish et al., *Medicare Beneficiaries Face Growing Out-Of-Pocket Burden For Specialty Drugs While In Catastrophic Coverage Phase*, 35 HEALTH AFF. 1564, 1564 (2016) (“the public’s top health policy priority for the president and Congress is ‘making sure that high-cost drugs are affordable to those who need them.’” (quoting *Kaiser Health Tracking Poll: October 2015*, KAISER FAM. FOUND. (Oct. 28, 2015), <https://www.kff.org/health-costs/poll-finding/kaiser-health-tracking-poll-october-2015/>). See also Karen Van Nuys et al., *Reining in pharmaceutical costs*, BROOKINGS (Aug. 3, 2017), <https://www.brookings.edu/blog/up-front/2017/08/03/reining-in-pharmaceutical-costs/> (“Most Americans believe that President Trump and the Congress should make lowering the cost of prescription drugs a priority.”); THE COUNCIL OF ECONOMIC ADVISERS, *REFORMING BIOPHARMACEUTICAL PRICING AT HOME AND ABROAD I* (Feb. 2018).

14. See, e.g., Katie Thomas, *The Fight Trump Faces Over Drug Prices*, N.Y. TIMES (Jan. 23, 2017), <https://www.nytimes.com/2017/01/23/health/the-fight-trump-faces-over-drug-prices.html> (“During the campaign, Mr. Trump joined his Democratic opponents, Mr. Sanders and Hillary Clinton, in calling for the federal government to be allowed to negotiate the price of drugs.”); Rachel Sachs et al., *Innovative Contracting for Pharmaceuticals and Medicaid’s Best-Price Rule*, 42 J. HEALTH POLITICS, POL’Y & L. 5, 5 (2017) (“Even in today’s polarized political landscape, a consensus has emerged: Americans deserve better value for their health care dollars. The focus on value sits well with liberals and conservatives, health insurers and pharmaceutical manufacturers, and a host of disparate stakeholder groups.”).

15. Ike Swelitz, *Trump says new health secretary will ‘get those prescription prices way down,’* STAT (Jan. 29, 2018), <https://www.statnews.com/2018/01/29/trump-azar-drug-prices/>; Katie Thomas & Reed Abelson, *Lower Drug Prices: New Proposals Carry Lots of Promises*, N.Y. TIMES (Feb. 9, 2018), <https://www.nytimes.com/2018/02/09/health/trump-drug-prices-medicare.html>. Former Food and Drug Administration Commissioner Scott Gottlieb has also expressed concern over high prescription drug prices and has been clearer with proposed policy solutions, including faster regulatory approvals and promoting increased generic drug market entry. See Sarah Jane Tribble & Liz Szabo, *FDA vows to combat high drug prices and companies ‘gaming the system,’* CNN MONEY (Feb. 16, 2018), <http://money.cnn.com/2018/02/16/news/economy/fda-drug-prices/index.html>; Nathaniel Weixel, *FDA chief becomes point man on drug prices*, THE HILL (Mar. 14, 2018), <http://thehill.com/business-a-lobbying/business-a-lobbying/378254-fda-chief-becomes-point-man-on-drug-prices>.

16. See generally U.S. DEP’T HEALTH & HUMAN SERVS., *AMERICAN PATIENTS FIRST: THE TRUMP ADMINISTRATION BLUEPRINT TO LOWER DRUG PRICES AND REDUCE OUT-OF-POCKET COSTS* (2018) (hereinafter *AMERICAN PATIENTS FIRST*) (outlining President Trump’s drug pricing priorities).

17. See Rachel Sachs, *Administration Outlines Plan To Lower Pharmaceutical Prices In Medicare Part B*, HEALTH AFF. BLOG (Oct. 26, 2018), <https://www.healthaffairs.org/doi/10.1377/hblog20181026.360332/full/>.

models to reform prescription drug pricing. The Department of Health and Human Services suggested value-based pricing, including indication-specific pricing, as possible opportunities to decrease high prescription drug prices. With a growing number of prescription drugs indicated for the treatment of several different conditions, especially in oncology,¹⁸ indication-specific pricing, one type of value-based pricing model, has received increased attention as a potential solution to high prescription drug prices.¹⁹

Indication-specific pricing, sometimes called indication-based pricing, is a value-based payment scheme where a prescription drug used to treat multiple conditions is priced based on the condition for which it is prescribed.²⁰ Indication-specific pricing sets higher prices for higher-value indications, and lower prices for lower-value indications.²¹ This scheme intends for prescription drug prices to better reflect value received by an individual patient.²² Despite its intent, an indication-specific pricing model may not actually accomplish the overarching policy goal of decreasing prescription drug spending and prices.²³ Further, there are several significant legal, regulatory, and policy barriers to implementing indication-specific pricing in the United States healthcare system.²⁴ This Note, therefore, will argue that lawmakers should not pursue an indication-specific pricing regime and should instead consider other methods to control prescription

18. See Peter B. Bach, *Indication-Specific Pricing for Cancer Drugs*, 312 J. AM. MED. ASS'N 1629, 1629 (2014). See generally STEPHEN D. PEARSON ET AL., INDICATION-SPECIFIC PRICING OF PHARMACEUTICALS IN THE UNITED STATES HEALTH CARE SYSTEM: A REPORT FROM THE 2015 ICER MEMBERSHIP POLICY SUMMIT (Mar. 2016) (analyzing the potential for implementing an indication-specific pricing regime in the United States).

19. See also Tara O'Neill Hayes, *Current Impediments to Value-Based Pricing for Prescription Drugs*, AM. ACTION F. (June 12, 2017), <https://www.americanactionforum.org/research/current-impediments-value-based-pricing-prescription-drugs/> (“With the unprecedented number of specialty medicines and oncology treatments expected over the next few years, the cost of prescription drugs will continue to be a concern for all stakeholders. QuintilesIMS Institute finds that 28 percent of new drugs currently being developed are oncology medicines, and nearly half of all drug spending in the U.S. will be for specialty medicines by 2021.”).

20. See PEARSON ET AL., *supra* note 18, at 2 (defining indication-specific pricing as “setting different prices for different indications or for distinct patient subpopulations eligible for treatment with a medication.”).

21. See Amitabh Chandra & Craig Garthwaite, *The Economics of Indication-Based Drug Pricing*, 377 NEW ENG. J. MED. 103, 103-04 (2017).

22. See *id.*

23. See *id.* (“relative to uniform pricing, indication-[specific] pricing results in higher prices for patients who benefit the most, higher utilization by patients who benefit least, higher overall spending, and higher manufacturer profits”). See also Part III, *infra*.

24. See generally PEARSON ET AL., *supra* note 18 (analyzing the potential for implementing an indication-specific pricing regime in the United States and discussing the legal, regulatory, and policy barriers to implementation).

drug prices and spending.²⁵

Part I provides background on value-based pricing models and defines indication-specific pricing of prescription drugs. Part II identifies and describes the legal and regulatory barriers to indication-specific pricing under Medicare, Medicaid, the 340B Drug Discount Program, and the Veterans Health Administration program. Part III presents the policy incentives raised by indication-specific pricing of prescription drugs in federal health insurance programs and discusses how it would impact the FDA regulatory system, off-label prescribing and promotion, and prescription drug prices. Ultimately, Part III argues that lawmakers should explore other methods, instead of indication-specific pricing, to decrease prescription drug prices and spending. Part IV suggests alternatives to indication-specific pricing that could be considered, introduces some initiatives that have already been raised, and recommends next steps for lawmakers.

I. VALUE-BASED PRICING MODELS AND INDICATION-SPECIFIC PRICING

A. *Value-Based Pricing of Prescription Drugs*

Currently in the United States, prescription drugs are generally reimbursed in a fee-for-service model.²⁶ Insurance companies reimburse per unit of the prescription drug without regard to outcome, indication, value to the patient, or any other factors. Critics of this payment model stress that not all patients receive the same benefit or value from a prescription drug even though they pay the same amount as patients who do benefit.²⁷ To avoid paying for ineffective treatments and to lower prescription drug prices, some advocates propose value-based pricing models.

Value-based pricing models link the price paid for a prescription drug with the expected or actual benefit to the patient.²⁸ There are several different types of

25. As the majority of prescription drugs for which indication-specific pricing is being proposed are high-priced brand name drugs with no generic alternative, typically for cancer treatment or other rare diseases, *see generally* Bach, *supra* note 18 (discussing indication-specific pricing for cancer drugs), this Note will focus only on the issues presented by indication-specific pricing of brand-name prescription drugs.

26. *See* Gregory Daniel et al., *Advancing Gene Therapies and Curative Health Care Through Value-Based Payment Reform*, HEALTH AFF. BLOG (Oct. 30, 2017), <https://www.healthaffairs.org/doi/10.1377/hblog20171027.83602/full/>. This is sometimes referred to as a “price-per-dose basis.” *See* Sachs et al., *supra* note 14, at 5.

27. *See* Sachs et al., *supra* note 14, at 6 (“[M]any patients receive little or no benefit from their prescription drugs—yet they pay precisely the same amount as those who do benefit.”).

28. *See* Daniel et al., *supra* note 26 (“[Value-based payment models] are designed to link payment more explicitly to a treatment’s value, expected or realized.”). *See generally* Sachs et al., *supra* note 14, at 7-14 (discussing how different value-based payment models work for prescription drugs).

value-based pricing models, differentiated based on the types of value measured (considering various contexts, benchmarks, or outcomes) in the model.²⁹ Value-based pricing models apply the determination of value to ultimately calculate the value-based price. The overall goal of value-based pricing is to incentivize providers to choose higher value, more effective prescription drugs, resulting in better outcomes for patients and lower overall healthcare spending.³⁰ Value-based pricing models therefore also encourage manufacturers to develop more effective and more profitable prescription drugs.

While the general concept of value-based pricing is simple, determining the value-based price of a prescription drug is exceedingly challenging. Most difficult is deciding what constitutes value and what factors represent this definition of value.³¹ Value is typically considered to be “the benefit of a treatment with respect to its cost,”³² but various factors must be taken into account in calculating the magnitude of this benefit with respect to cost. The determination of value can be made with respect to an individual patient (did this specific patient receive the intended benefit from this prescription drug?), to a sub-population (did the sub-population with a specific characteristic receive the intended benefit?),³³ or to a population as a whole (did this prescription drug lower the overall mortality or improve a health outcome to a predetermined benchmark related to clinical trial demonstrations?).³⁴ The value could be based on clinical measures, for example, a final treatment outcome, achieving a benchmark outcome in the course of treatment, or the disease requiring treatment.³⁵ This value could also be more subjective and include patient-centered benchmarks, such as patient satisfaction, increased quality of life, or decreased pain.

29. This Note focuses on indication-specific pricing, discussed in detail in Part I.B, *infra*. Other types of value-based payment models include outcome-based payment, drug licenses, and drug mortgages. For a detailed description of these value-based payment models, see Sachs et al., *supra* note 14, at 10-14.

30. See Daniel et al., *supra* note 26.

31. See *id.* at 2595-97 (“Value is an elusive target, and there’s no consensus about what dimensions should be taken into account.”). Several organizations have developed their own methodologies of evaluating prescription drugs and calculating their value to patients. See *id.* For example, Memorial Sloan Kettering Cancer Center’s framework focuses on the cancer drug’s mode of action, efficacy, and toxicity. *Id.* By contrast, the Institute for Clinical and Economic Review’s framework primarily looks at a prescription drug’s cost effectiveness in terms of cost per quality-adjusted life year and overall budget impact, but also looks at clinical effectiveness and other benefits in context. *Id.*

32. Bach, *supra* note 18, at 1629.

33. See *id.* (“What is the right price for any particular level of benefit? How should benefit be determined? What if the condition is rare? What if the average benefit is small but a subgroup of patients derives a large benefit?”).

34. See Hayes, *supra* note 19 (describing value-based payment agreements where the benchmarks were based on the results observed in clinical trials).

35. See Sachs et al., *supra* note 14, at 10-14 (discussing types of value-based pricing models).

B. Indication-Specific Pricing of Prescription Drugs

Prescription drugs are often used to treat more than one disease state or indication.³⁶ For example, Keytruda treats two different types of cancers and Avastin treats both cancer and macular degeneration.³⁷ However, despite the varied effectiveness of individual prescription drugs for different indications, prescription drug companies must charge the same price for the prescription drug regardless of the indication for which it is prescribed to a patient.

Indication-specific pricing would change this scheme by linking the price of the prescription drug to the condition for which it was prescribed.³⁸ In indication-specific pricing models, prescription drug manufacturers are paid more when their prescription drug is used to treat an indication for which the product is more effective or has a higher value (high-value indications) than when it is used to treat an indication for which the product is less effective or has a lesser value for the patient (low-value indications).³⁹ For example, in an indication-specific pricing regime, Keytruda would cost a different price when it is prescribed for the treatment of advanced non-small cell lung cancer than it is for advanced melanoma, based on its effectiveness in treating the condition.⁴⁰ The determinations of value or effectiveness are typically based on the data collected during clinical trials.⁴¹ Depending on an individual's prescription drug coverage, these higher prices for high-value indications are likely less affordable and less accessible as a result.⁴² Conversely, indication-specific pricing sets lower prices for lower-value indications, resulting in them being more affordable, more accessible, and used more by patient populations who receive a comparatively lesser benefit from them.⁴³ Indication-specific pricing models can be a pure indication-specific pricing regime, meaning that each different indication has a different price, or a partially indication-specific pricing regime, generally meaning

36. See PEARSON ET AL., *supra* note 18, at 6 (“A multi-indication medication is a drug that is approved or prescribed for more than one condition or for a single condition with multiple identifiable patient sub-groups that have important differences in baseline risk and/or treatment outcomes.”); Chandra & Garthwaite, *supra* note 21, at 103 (“in oncology, for instance, response to a treatment varies with the type of tumor and stage of disease.”).

37. See Sachs et al., *supra* note 14, at 7-8.

38. See Sachs et al., *supra* note 14, at 7-8; Chandra & Garthwaite, *supra* note 21, at 103; PEARSON ET AL., *supra* note 18, at 2 (defining indication-specific pricing as “setting different prices for different indications or for distinct patient subpopulations eligible for treatment with a medication.”).

39. See Chandra & Garthwaite, *supra* note 21, at 103.

40. See Sachs et al., *supra* note 14, at 7-8; KEYTRUDA © (pembrolizumab), KEYTRUDA.COM (Nov. 2017), <https://www.keytruda.com> (listing the FDA-approved indications of Keytruda)

41. Hayes, *supra* note 19.

42. See Chandra & Garthwaite, *supra* note 21, at 103-04.

43. See *id.*

that indication-specific prices are combined into a weighted-average price.⁴⁴

Some countries have implemented indication-specific pricing regimes for prescription drugs, either in part or in a pure form.⁴⁵ Italy has adopted a pure indication-specific pricing regime for some prescription drugs, including some cancer drugs and an anti-inflammatory prescription drug, through the use of managed entry agreements.⁴⁶ Managed entry agreements are contracts between payers and a pharmaceutical company that allows a prescription drug to be covered subject to certain conditions.⁴⁷ Italy permits three types of managed entry agreements, each involving some sort of refund to the payer for insufficient outcomes.⁴⁸ Some of these managed entry agreements consider different outcomes (and thus different refunds) for different indications, resulting in a *de facto* indication-specific price.⁴⁹ Even with some indication-specific pricing and outcomes-based pricing arrangements, Italy has not seen any resulting decrease in the cost of prescription drugs.⁵⁰ Other countries have incorporated the value of each indication of a drug into their prescription drug prices, resulting in a partially indication-specific pricing regime. Australia has used weighted-average prices for prescription drugs with multiple indications, combining the different value-based prices for each indication into a single weighted average price.⁵¹ The United Kingdom allows prescription drugs to increase their reimbursement price once if a prescription drug manufacturer identifies a new high-value indication.⁵²

In theory, indication-specific pricing may help better allocate prescription drugs, incentivizing prescribing high-value indications instead of less effective treatments and incentivizing prescription drug manufacturers to develop more effective treatments and support their products with demonstrations of effectiveness.⁵³ However, indication-specific pricing would face several legal barriers to implementation in federal health insurance programs in the United

44. See PEARSON ET AL., *supra* note 18, at 11-12 (describing different variations of indication-specific pricing models).

45. See *id.* at 12.

46. See *id.* at 13; Mathias Flume, et al., *Feasibility and Attractiveness of Indication Value-based Pricing in Key EU Countries*, 4 J. MARKET ACCESS & HEALTH POL'Y (2016).

47. Jacoline C. Bouvy et al., *Managed Entry Agreements for Pharmaceuticals in the Context of Adaptive Pathways in Europe*, 9 FRONTIERS IN PHARMACOLOGY 280, 280 (2018).

48. See Flume, et al., *supra* note 46.

49. See *id.*

50. See Noemie Bisserbe, *For New Trump Drug Plan, a Cautionary Tale in Italy*, WALL ST. J. (Apr. 17, 2018), <https://www.wsj.com/articles/italy-serves-cautionary-lesson-for-new-trump-drug-plan-1523959644> (discussing the results of outcomes-based contracts).

51. See PEARSON ET AL., *supra* note 18, at 13 (describing different variations of indication-specific pricing models).

52. See *id.*

53. See generally Susan Abedi, *Indication-Based Pricing- The Good, The Bad, and the Ugly*, IMS CONSULTING GROUP (June 2016), http://www.ehcca.com/presentations/PharmaMM/abedi_c.pdf.

States.⁵⁴ Additionally, the policy effects of indication-specific pricing are debated.⁵⁵ There are several reasons advocates support indication-specific pricing, including having prescription drug prices better reflect their value to patients and incentivizing manufacturers to develop high-value treatments. Supporters of indication-specific pricing assert that this regime would decrease spending for high-cost prescription drugs, while critics claim it will increase spending.⁵⁶

The remainder of this Note will detail the legal, regulatory, and policy barriers to implementing an indication-specific pricing regime in the United States, particularly in federal health insurance programs.⁵⁷ Further, this Note will demonstrate that although these barriers may not be insurmountable, indication-specific pricing is not the appropriate solution to high prescription drug spending and prices in the United States.

II. INDICATION-SPECIFIC PRICING IN FEDERAL HEALTH INSURANCE PROGRAMS

Implementing an indication-specific pricing regime would require rethinking the prescription drug pricing and reimbursement models of federal government health insurance programs. The federal government pays for healthcare, including prescription drugs, through several independent health insurance programs. Each program has, among other things, different eligibility requirements, different benefits packages, and different means of determining the price, provision, and reimbursement of prescription drugs. These systems pose different barriers to indication-specific pricing. This Part introduces four of the major federal health insurance programs purchasing prescription drugs (Medicare, Medicaid, the 340B Drug Discount Program, and the Veterans Health Administration); describes how each program structures pricing, reimbursement, and payment for prescription drugs; and discusses the barriers to implement an indication-specific pricing

54. See Part II, *infra*. See also Bach, *supra* note 18, at 1630.

55. Compare Bach, *supra* note 18, with Chandra & Garthwaite, *supra* note 21.

56. See Part III, *infra*. See also Chandra & Garthwaite, *supra* note 21, at 103 (“Supporters hope that such a system will re-duce prices for low-value indications but that prices for high-value indications will not increase.” (citing Bach, *supra* note 18, at 1629-30)); Chandra & Garthwaite, *supra* note 21, at 103-04 (arguing that indication-specific pricing would increase overall drug spending); PEARSON ET AL., *supra* note 18, at 8-10 (listing the risks and benefits of indication-specific pricing of prescription drugs to payers and prescription drug manufacturers).

57. In considering indication-specific pricing as a solution to high prescription drug prices and spending, this Note assumes that if an indication-specific pricing model were allowed or adopted, all prescription drugs purchased in the United States by federal health insurance programs would now be subject to an indication-specific price. Further, this indication-specific price would reflect the value of the treatment to a patient population relative to other treatments. While this is ideally the case, adopting this policy does not guarantee that the negotiated price would in fact accurately reflect the actual value of a treatment received by a patient. This may affect the degree of the impact and incentive effects of indication-specific pricing. Regardless, the legal and regulatory barriers to indication-specific pricing and the policy incentives identified remain significant.

regime for prescription drugs in each program.

A. Medicare

Medicare provides health insurance coverage for people age sixty-five and over, some younger people with disabilities, and people with end-stage renal disease.⁵⁸ Medicare currently provides health insurance for approximately fifty-five million people in the United States,⁵⁹ covering \$672.1 billion in healthcare services in 2016.⁶⁰ Medicare alone comprises approximately 40 percent of the pharmaceutical market in the United States.⁶¹

The Medicare program covers different healthcare services under different parts of the program.⁶² Medicare Part A, sometimes referred to as Hospital Insurance, covers healthcare during certain inpatient stays.⁶³ Prescription drugs used during a hospital stay are included in the broader reimbursement for the inpatient stay.⁶⁴ Medicare Part B primarily covers services provided in a doctor's office.⁶⁵ Prescription drugs administered during a physician office visit or in a hospital outpatient clinic are included under Medicare Part B.⁶⁶ Medicare Part C, also called Medicare Advantage Plans, provides coverage for Medicare Part A and Medicare Part B benefits, and often prescription drug coverage, through a private company contracting with Medicare.⁶⁷ Medicare Part D provides prescription drug

58. See *What's Medicare*, MEDICARE.GOV: THE OFFICIAL U.S. GOVERNMENT SITE FOR MEDICARE, <https://www.medicare.gov/sign-up-change-plans/decide-how-to-get-medicare/whats-medicare/what-is-medicare.html>; *Health Policy Brief: Medicare Part D*, HEALTH AFF. (Aug. 10, 2017), https://www.healthaffairs.org/doi/10.1377/hpb20171008.000172/full/healthpolicybrief_172.pdf [hereinafter *Medicare Part D Brief*].

59. See *Health Policy Brief: Implementing MACRA*, HEALTH AFF. (Mar. 27, 2017), <https://www.healthaffairs.org/doi/10.1377/hpb20170327.272560/full/> (55 million people on Medicare) [hereinafter *MACRA Brief*]. See also *The Medicare Part D Prescription Drug Benefit*, KAISER FAM. FOUND. (Oct. 2, 2017), <https://www.kff.org/medicare/fact-sheet/the-medicare-prescription-drug-benefit-fact-sheet/> (59 million people on Medicare).

60. *NHE Fact Sheet*, CTRS. FOR MEDICARE & MEDICAID SERVS. (Dec. 6, 2017), <https://www.cms.gov/research-statistics-data-and-systems/statistics-trends-and-reports/nationalhealthexpenddata/nhe-fact-sheet.html>.

61. See Greg D'Angelo, *The VA Drug Pricing Model: What Senators Should Know*, HERITAGE FOUND.: WEBMEMO (Apr. 11, 2007).

62. See *What's Medicare*, *supra* note 58.

63. See *id.* (explaining Medicare Part A “covers inpatient hospital stays, care in a skilled nursing facility, hospice care, and some home health care.”).

64. See *Health Policy Brief: Medicare Part B*, HEALTH AFF. (Aug. 10, 2017), https://www.healthaffairs.org/doi/10.1377/hpb20171008.000171/full/healthpolicybrief_171.pdf [hereinafter *Medicare Part B Brief*].

65. See *What's Medicare*, *supra* note 58 (explaining Medicare Part B covers “certain doctors’ services, outpatient care, medical supplies, and preventive services.”).

66. See *Medicare Part B Brief*, *supra* note 64; *Medicare Part D Brief*, *supra* note 58.

67. See *What's Medicare*, *supra* note 58.

coverage through contracts with private companies and Medicare Advantage Plans.⁶⁸ Each part of Medicare calculates prescription drug prices and reimbursement rates differently, posing various challenges to indication-specific pricing. As the majority of prescription drug spending through Medicare occurs under Parts B and D,⁶⁹ the following sections further detail their prescription drug pricing schemes.

1. Medicare Part B

Medicare Part B covers prescription drugs prescribed and administered in outpatient clinics and physician's offices.⁷⁰ These include prescription drugs administered by injection or intravenously in a physician's office or hospital outpatient setting and some oral cancer drugs that also have intravenous forms.⁷¹ Medicare Part B must cover all prescription drugs that are "reasonable and necessary for the diagnosis or treatment of illness or injury;" price cannot be taken into account while deciding reimbursement coverage.⁷² Medicare Part B spending on prescription drugs totaled approximately \$25 billion in 2015, at least half of which was spent on cancer drugs.⁷³

Prescription drug manufacturers participating in Medicare Part B are required to report prescription drug prices to the federal government on a per-unit basis without a reported indication.⁷⁴ Prescription drugs provided under Medicare Part B are reimbursed at the average sales price to a non-federal government payer plus 6 percent paid as a handling fee to doctors.⁷⁵ Patients are personally responsible for paying a 20 percent co-insurance for all prescription drugs under Medicare Part

68. *See id.*

69. *See* Rachel E. Sachs, *Delinking Reimbursement*, 102 MINN. L. REV. 2307, 2314 (2018).

70. *See Medicare Part B Brief, supra* note 64; *Medicare Part D Brief, supra* note 58.

71. White, *supra* note 4, at 194-95.

72. *See* Sachs, *supra* note 17 (quoting 42 U.S.C. § 1395y(a)(1)(A)).

73. Sachs, *supra* note 69, at 2314.

74. *See* Daniel et al., *supra* note 26. Manufacturers must report the average sales price and average wholesale price of their products quarterly by the National Drug Code (NDC), and physicians report the NDC and/or the Healthcare Common Procedure Coding System (HCPCS) code for the product administered, but the indication for which the prescription drug was eventually prescribed by physicians is not reported. *See* DEP'T OF HEALTH & HUMAN SERVS., OFFICE OF INSPECTOR GENERAL, AVERAGE SALES PRICES: MANUFACTURER REPORTING AND CMS OVERSIGHT 3-4 (Feb. 2010); Report to the Congress: Medicare and the Health Care Delivery System (June 2016). *See also* CTRS. FOR MEDICARE & MEDICAID SERVS., HEALTHCARE COMMON PROCEDURE CODING SYSTEM (HCPCS) LEVEL II CODE MODIFICATION REQUEST PROCESS 2019 UPDATE (APR. 2017), <https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/Downloads/HCPCS-Application.pdf> (briefly advising on HCPCS coding through Medicare for prescription drugs).

75. *See* 42 U.S.C. § 1395w-3a (dictating average sales price methodology); 42 C.F.R. § 414.804 (providing further regulations on average sales price methodology); *Medicare Part B Brief, supra* note 64.

B with no upper limit on out-of-pocket spending.⁷⁶

Medicare Part B poses a few significant challenges to adopting an indication-specific pricing model. First, the price reporting requirements for prescription drug manufacturers could cause a compliance issue; as indication-specific pricing by definition is not a price-per-unit model, this regulation would have to be modified in order for an indication-specific pricing model to be possible.⁷⁷ The regulation could be changed to require a price-per-unit-per-indication model, or otherwise repealed or modified to allow indication-specific pricing. Further, because prices are reported by product, not indications for the product,⁷⁸ the current reporting regime would need to be amended in order to include the indication for the reported code. Second, there is no requirement for physicians to report the indication for which they prescribe a prescription drug. In order for an indication-specific pricing regime to be implemented, a law or regulation mandating physicians to report the indication associated with each prescription would be necessary. Third, Medicare Part B reimburses based on the average sales price not differentiated by indication.⁷⁹ Average sales price would have to be redefined as average sales price per indication, or the formula would have to be otherwise modified for an indication-specific pricing regime to be implemented.

An indication-specific pricing scheme also would not address the questionable policy incentives for physicians under Medicare Part B. The 6 percent handling fee for physicians incentivizes physicians to prescribe prescription drugs with higher costs.⁸⁰ The prescription drug with the higher price would theoretically be the most effective treatment for the specific indication. This could effectively ensure that physicians make rational choices and maximize the value of their prescribing. However, with further incentives for doctors to prescribe the higher-priced prescription drug, prescription drug spending may not decrease under an indication-specific pricing model. In order to lessen the incentive for physicians, the Centers for Medicare and Medicaid Services (CMS) proposed a demonstration

76. See *id.*; Bach & Pearson, *supra* note 8, at 2503 (“the current policy of flat 20% co-insurance without an upper limit has put some highly effective but expensive drugs out of reach for the roughly 6 million Medicare beneficiaries who have no supplemental insurance.”).

77. See Daniel et al., *supra* note 26 (“Value-based payment arrangements by definition depart from a per-unit price, but current statutory and regulatory provisions are not designed to capture such arrangements. Manufacturers could be exposed to compliance risk when they seek to reflect a value-based arrangement in their price reporting, and reflecting a value-based arrangement in a per-unit metric could result in unintended reimbursement and payment consequences.”).

78. See *National Drug Code Directory*, FOOD AND DRUG ADMIN. (Nov. 2017), <https://www.fda.gov/drugs/informationondrugs/ucm142438.htm>. See also MEDICARE PAYMENT ADVISORY COMM’N, REPORT TO THE CONGRESS: MEDICARE AND THE HEALTH CARE DELIVERY SYSTEM 131 (June 2016) (listing multiple indications in relation to one HCPCS code).

79. See 42 U.S.C. § 1395w-3a (dictating average sales price methodology not taking into account indication); *Medicare Part B Brief*, *supra* note 64.

80. See *Medicare Part B Brief*, *supra* note 64.

project in 2016 (which was never implemented) that would have changed physician reimbursement for prescription drugs under Medicare Part B to a flat handling fee of \$16.80 plus 2.5 percent of the average sales price.⁸¹ This proposal was intended to maintain the same aggregate prescription drug spending under Medicare Part B while increasing the handling fee for lower priced prescription drugs.⁸² President Trump has also proposed a similar reform.⁸³ While changing this formula would address physician incentives to some extent, it would do little to help beneficiaries afford prescription drugs. Reforms to prescription drug pricing under Medicare Part B must consider this formula and the existing reimbursement model so as not to exacerbate the existing incentives for physicians to prescribe high priced prescription drugs and increase drug spending.

2. Medicare Part D

Medicare Part D is the largest federal program paying for prescription drugs.⁸⁴ Medicare Part D covers exclusively prescription drugs purchased at pharmacies by consumers.⁸⁵ Medicare Part D plans are run by private companies contracting with the federal government.⁸⁶ Medicare pays private companies running the Medicare Part D plans a fixed grant to help pay for all prescription drugs used by covered beneficiaries instead of paying for specific prescription drugs.⁸⁷ Everyone on Medicare has access to Medicare Part D and in 2017 over forty million people enrolled in Medicare Part D plans.⁸⁸ The largest Medicare Part D plans represent approximately 21 percent of Medicare Part D recipients.⁸⁹ Consumers eligible for both Medicare and Medicaid receive their prescription drug coverage under Medicare Part D.⁹⁰ Total drug spending under Medicare Part D in 2015 was

81. See *id.* See also Deborah Schrag, *Reimbursing Wisely? CMS's Trial of Medicare Part B Payment Reform*, 374 NEW ENG. J. MED. 2101, 2101 (2016).

82. See *Medicare Part B Brief*, *supra* note 64.

83. See Sachs, *supra* note 17.

84. See *Medicare Part D Brief*, *supra* note 67.

85. See *id.*

86. Michael Adelberg & Marissa Schlaifer, *The Other Side of Managed Competition: The Tension Between Protection And Innovation In Medicare Advantage And Part D Benefits*, HEALTH AFF. BLOG (Dec. 8, 2017), <https://www.healthaffairs.org/doi/10.1377/hblog20171205.156064/full/> (“Medicare Advantage and Medicare Part D are prime examples of managed competition markets, where the government provides services by contracting with private entities to serve program beneficiaries in a regulated market.”).

87. See *Medicare Part B Brief*, *supra* note 64.

88. See *The Medicare Part D Prescription Drug Benefit*, *supra* note 59 (42 million people enrolled on Medicare Part D plans).

89. See *Medicare Part D Brief*, *supra* note 67.

90. See *The Medicare Part D Prescription Drug Benefit*, *supra* note 59. This allocation of Medicaid-eligible individuals to Medicare Part D prescription drug coverage raises its own prescription drug spending problems, as on average “Medicare Part D pays . . . 73% more than

approximately \$135 billion.⁹¹

CMS requires all Medicare Part D plans to cover at least two prescription drugs in each therapeutic class and all drugs in six classes, called protected classes, which include antidepressants, antiretrovirals, antipsychotics, anticonvulsants, immunosuppressants (to prevent organ transplant rejection), and antineoplastics (a type of cancer treatment).⁹² There is still substantial variation between Medicare Part D plans with regard to drugs included on the formularies and copayments (or cost-sharing amounts for which patients are responsible at the point of service).⁹³ The formularies of Medicare Part D plans generally tier drugs, differentiating preferred prescription drugs (which are associated with lower copayments) from more expensive non-preferred prescription drugs.⁹⁴ Beneficiaries cover 25 percent of prescription drug costs until the catastrophic cap of \$4,950 in beneficiary spending.⁹⁵ After reaching the catastrophic cap, under a provision of the Affordable Care Act to be implemented by 2020, beneficiaries are responsible for 5 percent of prescription drug costs, with the Medicare Part D plan covering 15 percent and a federal government reinsurance subsidy covering the remaining 80 percent.⁹⁶

Medicare is prohibited by law from negotiating or setting prices for Medicare Part D.⁹⁷ However, individual Medicare Part D plans can and do negotiate prices

Medicaid and 80% more than [the Veterans Health Administration] . . . for the same brand-name drugs.” Micah Vitale, Note, *The Rise in Prescription Drug Prices: The Conspiracy Against The Cure*, 20 QUINNIAC HEALTH L. J. 75, 92 (2017) (quoting MARC-ANDRÉ GAGNON & SIDNEY WOLFE, MIRROR, MIRROR ON THE WALL: MEDICARE PART D PAYS NEEDLESSLY HIGH BRAND-NAME DRUG PRICES COMPARED WITH OTHER OECD COUNTRIES AND WITH U.S. GOVERNMENT PROGRAMS 12 (2015), <http://carleton.ca/sppa/wp-content/uploads/Mirror-Mirror-Medicare-Part-D-Released.pdf>.) (alteration in original). Because Medicare Part D pays more for drugs than Medicaid, the system has essentially chosen to spend more for prescription drugs than is necessary. Some scholars have proposed that consumers eligible for both Medicare and Medicaid, sometimes called “dual-eligibles,” should be moved back to Medicaid for their prescription drug coverage, arguing that it would lead to lower prescription drug spending and better access to prescription drugs for patients. See Kevin Outterson & Aaron S. Kesselheim, *How Medicare Could Get Better Prices on Prescription Drugs*, HEALTH AFF. W832, w834-35 (2009).

91. See Sachs, *supra* note 69, at 2314.

92. *Medicare Part D Brief*, *supra* note 67; CTRS. FOR MEDICARE & MEDICAID SERVS., MEDICARE PRESCRIPTION DRUG BENEFIT MANUAL 28 (2016), available at <https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Part-D-Benefits-Manual-Chapter-6.pdf>.

93. Adelberg & Schlaifer, *supra* note 86.

94. See *Medicare Part D Brief*, *supra* note 67.

95. See *id.*

96. See *id.*

97. 42 U.S.C. § 1395w-111(i) (2012). See also *Medicare Part D Brief*, *supra* note 67; Sachs, *supra* note 69, at 2325-26 (“Often referred to as the noninterference clause, the statute provides that the Secretary of Health and Human Services (HHS) “may not interfere with the negotiations between drug manufacturers and pharmacies and [Prescription Drug Plan] sponsors and “may not require a

with prescription drug manufacturers.⁹⁸ The cost-sharing model and the competition between Medicare Part D plans, both in attracting consumers and in bidding for federal government contracts, incentivize them to negotiate prescription drug prices as low as possible.⁹⁹ Prescription drug spending, including for high-cost brand name prescription drugs, is a concern under Medicare Part D. In 2013, while the top ten drugs paid for by Medicare Part D plans were all generics (306.6 million claims totaling \$4.14 billion), the top ten most expensive were all brand name prescription drugs (54.63 million claims totaling \$19.78 billion).¹⁰⁰

The barriers to implementing indication-specific pricing in Medicare Part D are perhaps more formidable than those present in Medicare Part B. The laws forbidding Medicare from negotiation with prescription drug manufacturers would pose a challenge to implementing an effective indication-specific pricing scheme in Medicare Part D. Because Medicare cannot negotiate as a whole, even though individual Medicare Part D plans can negotiate with prescription drug manufacturers, Medicare Part D plans cannot leverage the buying power of the whole Medicare population.¹⁰¹ This negotiation model weakens the bargaining power of Medicare Part D to lower prescription drug prices, likely making prices higher than they would be if Medicare negotiated as a whole. However, this limitation alone is not the most substantial barrier to lowering prescription drug prices and spending.

The requirement that Medicare Part D plans cover all prescription drugs in six protected classes, which includes cancer drugs, further challenges the ability for indication-specific pricing to lower prescription drug spending.¹⁰² This regulation significantly weakens Medicare Part D plans' negotiating power, leaving the prescription drug manufacturers with all the bargaining power and forcing manufacturers to accept high prices for these drugs.¹⁰³ Even if the indication-

particular formulary or institute a price structure for the reimbursement of covered part D drugs.”).

98. See *Medicare Part D Brief*, *supra* note 67.

99. See Theodore T. Lee et al., *The Politics of Medicare and Drug Price Negotiation (Updated)*, HEALTH AFF. BLOG (Sept. 19, 2016), <https://www.healthaffairs.org/doi/10.1377/hblog20160919.056632/full/>.

100. See Nicole M. Gastala et al., *Medicare Part D: Patients Bear The Cost Of 'Me Too' Brand Name Drugs*, 35 HEALTH AFF. 1237, 1238 (2016) (citing *Press release, CMS releases prescriber-level Medicare data for first time*, CTRS. FOR MEDICARE & MEDICAID SERVS. (Apr. 30, 2015), <https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2015-Fact-sheets-items/2015-04-30.html>)).

101. See *Medicare Part D Brief*, *supra* note 67.

102. See *id.*

103. See Thomas, *supra* note 14 (“‘You get your largest negotiating power from your ability to walk away,’ said Dr. Aaron S. Kesselheim, an associate professor at Harvard Medical School who has written frequently on drug prices.”). See also Sachs, *supra* note 69, at 2326 (“Medicare might be able to achieve some savings where there is already market competition and where Medicare is permitted to cover two drugs in that class, although it is difficult to see why private plans have not negotiated such deals already. But for the six protected classes in which Medicare must cover all

specific price somewhat lowered the prices, the lack of negotiation power undermines the ability of Medicare Part D plans to negotiate a price truly reflecting the value. With this mandate still in place, not only would insurers be unable to demand an indication-specific price for a high-cost cancer drug based on its value to a patient population, but they would still be forced to accept inflated prices for prescription drugs in these protected classes.

While the negative physician incentives present in Medicare Part B are not present in Medicare Part D, the negative incentives for patients are significant. Instead of the 20 percent co-insurance under Medicare Part B, beneficiaries under Medicare Part D are responsible for a 25 percent co-insurance up to the catastrophic cap of \$4,950 and then 5 percent co-insurance after reaching the catastrophic cap.¹⁰⁴ As many prescription drugs cost more than the catastrophic cap,¹⁰⁵ many consumers face a significant and possibly prohibitive out-of-pocket spending requirement. An indication-specific pricing regime would do nothing to address the cost to patients unless the indication was less effective. If the relevant indication of the prescription drug was a relatively less effective than other treatments, it would cost relatively less and be more affordable to the patient at the point of service. However, high-cost, high-value indications of prescription drugs would remain expensive to both consumers and to the system, and an indication-specific pricing model would give manufacturers and patients no incentives to lower prices or seek better care options.

In addition to not addressing the affordability of drugs for patients, an indication-specific pricing regime would do nothing to decrease the government's overall prescription drug spending. Under Medicare Part D, a federal government subsidy pays for 80 percent of prescription drug costs after the catastrophic cap is reached; the reinsurance, or subsidy, portion of Medicare Part D is the fastest growing Medicare Part D cost as so many prescription drugs now cost thousands of dollars annually.¹⁰⁶ An indication-specific pricing regime would do nothing to decrease or slow the reinsurance costs. Reforms to Medicare Part D should both slow spending and improve patient access, and an indication-specific pricing regime would accomplish neither.

B. Medicaid

Medicaid is the federal government health insurance program that provides health insurance coverage for low-income people in the United States,¹⁰⁷ covering

products, or for expensive new drugs with few, if any, substitutes, Medicare cannot walk away from the table if it does not like the deal companies are offering.”).

104. See *Medicare Part D Brief*, *supra* note 67.

105. See *id.*

106. *Id.*

107. See *About Us*, MEDICAID.GOV, <https://www.medicaid.gov/about-us/index.html>.

approximately seventy million Americans.¹⁰⁸ It is one of the largest payers for healthcare in the United States.¹⁰⁹ Medicaid is administrated by the states and jointly funded by the states and the federal government.¹¹⁰

Medicaid comprises approximately 20 percent of the prescription drug market.¹¹¹ Prescription drugs are a small but growing portion of Medicaid spending (6 percent to 9 percent from 2010 to 2015).¹¹² The growth rate of Medicaid prescription drug spending in 2014 outpaced that of overall prescription drug spending in the United States.¹¹³ While prescription drug coverage is an optional benefit under Medicaid, all states currently cover prescription drug costs for Medicaid beneficiaries.¹¹⁴ Most states charge copayments for prescription drugs purchased under Medicaid, but these copayments are very low, capped at a few dollars per prescription and less than \$30 per month.¹¹⁵

The price Medicaid pays for prescription drugs is regulated by the Medicaid Drug Rebate Program and the Medicaid Best Price Rule.¹¹⁶ Under the Medicaid Drug Rebate Program, prescription drug manufacturers receive Medicaid coverage for essentially all of their prescription drug products in exchange for agreeing with the Department of Health and Human Services to provide rebates to Medicaid, the 340B Drug Discount Program, and the Department of Veterans Affairs.¹¹⁷ As long as the prescription drug manufacturer participates in the Medicaid Drug Rebate

108. See *Medicaid*, MEDICAID.GOV, <https://www.medicaid.gov/medicaid/index.html> (68 million covered as of the October 2017 open enrollment period); *Medicaid State Fact Sheets*, KAISER FAM. FOUND. (June 16, 2017), <https://www.kff.org/interactive/medicaid-state-fact-sheets/> (“Medicaid and the Children’s Health Insurance Program (CHIP) provide health and long-term care coverage to more than 70 million low-income children, pregnant women, adults, seniors, and people with disabilities in the United States.”).

109. See *About Us*, MEDICAID.GOV, *supra* note 107.

110. See *Medicaid*, *supra* note 108.

111. See *Health Policy Brief: Veterans Health Administration*, HEALTH AFF. (Aug. 10, 2017), https://www.healthaffairs.org/doi/10.1377/hpb20171008.000174/full/healthpolicybrief_174.pdf [hereinafter *Veterans Health Administration Brief*].

112. See David Dranove et al., *A Dose of Managed Care: Controlling Drug Spending in Medicaid* 9 (National Bureau of Economic Research Working Paper 23956, Oct. 2017), <http://www.nber.org/papers/w23956>.

113. See Hefei Wen et al., *Number Of Medicaid Prescriptions Grew, Drug Spending Was Steady In Medicaid Expansion States*, 35 HEALTH AFF. 1604, 1604 (2016) (citing Anne B. Martin et al., *National Health Spending in 2014: Faster Growth driven By Coverage Expansion and Prescription Drug Spending*, 35 HEALTH AFF. 150 (2016)).

114. See *Prescription Drugs*, MEDICAID.GOV, <https://www.medicaid.gov/medicaid/prescription-drugs/> (accessed Dec. 31, 2017).

115. See *id.* (presenting the prescription drug payments and copayments under Medicaid in each state).

116. See *Health Policy Brief: Medicaid Best Price*, HEALTH AFF. (Aug. 10, 2017), <https://www.healthaffairs.org/doi/10.1377/hpb20171008.000173/full/> [hereinafter *Medicaid Best Price Brief*].

117. See *id.*

Program, states must cover all of the manufacturer's prescription drugs approved by the Food and Drug Administration (FDA).¹¹⁸ Because prescription drug manufacturers who do not participate in the Medicaid Drug Rebate Program are excluded from participating in all federal government health insurance programs (a massive share of the prescription drug market), prescription drug manufacturers are basically required to participate.¹¹⁹

The value of the rebates is set by statute.¹²⁰ Rebates are collected directly by Medicaid.¹²¹ State Medicaid programs are allowed to negotiate further discounts in addition to these rebates.¹²² For the majority of new, high-cost prescription drugs (innovator drugs), Medicaid is entitled to a minimum of a 23.1 percent rebate off the average manufacturer price.¹²³ The rebate is also subject to the Medicaid Best Price Rule: if the lowest price offered by the prescription drug manufacturer is lower than the price Medicaid would pay for the drug after the guaranteed rebate, then Medicaid is entitled to pay for the lower price – the “best price.”¹²⁴ Certain programs are excluded from the Medicaid Best Price Rule, including Medicare Part D,¹²⁵ Medicare Advantage plans,¹²⁶ the 340B Drug Discount Program,¹²⁷ and the Veterans Health Administration.¹²⁸ This means that these programs can receive lower prices than those paid by Medicaid without triggering the Medicaid Best Price Rule.

Medicaid raises significant legal and regulatory challenges to implementing

118. 42 U.S.C. 1396r–8. See Manatt Phelps & Phillips LLP, *Efforts to Cut Drug Prices in Medicaid*, LEXOLOGY (Feb. 27, 2018), <https://www.lexology.com/library/detail.aspx?g=9f8fef25-d178-40f6-9c0b-9ee511c018e9>.

119. See *Medicaid Best Price Brief*, *supra* note 116.

120. See *Drug Rebate Program*, MEDICAID.GOV, <https://www.medicaid.gov/medicaid/prescription-drugs/medicaid-drug-rebate-program/index.html>.

121. See *Medicaid Best Price Brief*, *supra* note 116.

122. See David Blumenthal & David Squires, *Drug Price Control: How Some Government Programs Do It*, COMMONWEALTH FUND (May 10, 2016), <http://www.commonwealthfund.org/publications/blog/2016/may/drug-price-control-how-some-government-programs-do-it>.

123. See *Medicaid Best Price Brief*, *supra* note 116; Sachs et al., *supra* note 14, at 7. Some other products are subject to different minimum rebates: blood clotting factors and drugs approved by the FDA for exclusively pediatric indications are subject to a minimum rebate of 17.1 percent off the average manufacturer price, non-innovator drugs are subject to a minimum rebate of 13 percent off the average manufacturer price per unit. See *Drug Rebate Program*, *supra* note 120.

124. See Sachs et al., *supra* note 14, at 7; *Medicaid Best Price Brief*, *supra* note 116. See also 42 U.S.C. § 1396r-8 (Medicaid Drug Rebate Program and Best Price Rule statute).

125. See Sachs et al., *supra* note 14, at 7.

126. See *id.*

127. See *Health Policy Brief: The 340B Drug Discount Program*, HEALTH AFF., (Sept. 14, 2017), https://www.healthaffairs.org/doi/10.1377/hpb20171409.000175/listitem/healthpolicybrief_175.pdf [hereinafter *340B Brief*].

128. See *Veterans Health Administration Brief*, *supra* note 111.

an indication-specific pricing model.¹²⁹ First, the Medicaid Best Price Rule applies to the lowest price of each prescription drug, not each indication for a prescription drug.¹³⁰ Implementing an indication-specific pricing regime without any modification or guidance with respect to the Medicaid Best Price Rule would require prescription drug manufacturers to accept the lowest price for any indication of a product, thereby providing the prescription drug for high-value indications at the cost for its lowest-value indications.¹³¹ With a threat of the price assigned to a lower value indication applying across the board to all indications of the product, prescription drug manufacturers may be less likely, even disincentivized, to research or seek approval for these lower value indications.

Additionally, as these Medicaid rebates are calculated based on the average manufacturer price of a prescription drug, not the average manufacturer price of a specific indication of a prescription drug,¹³² modifications to how Medicaid calculates prescription drug prices would be necessary if implementing a pure indication-specific pricing regime. Several potential solutions to this problem have been recommended, including adopting a partial indication-specific pricing regime (an average weighted price incorporating indication-specific prices), product differentiation (seeking FDA approval for each indication as a different drug product), and CMS redefining a drug as “a chemical compound approved for a particular indication.”¹³³

Despite the guaranteed rebates and the Medicaid Best Price Rule limiting prescription drug prices, Medicaid spending on prescription drugs would likely increase under an indication-specific pricing regime. As Medicaid prices are based on the average sales price to other insurers, who would also have indication-specific prices and likely pay high prices for high-value indications, even the lower price paid by Medicaid would likely increase. This is further aggravated by the law under the Medicaid Drug Rebate Program requiring Medicaid and other federal health insurance programs to cover all FDA-approved drugs by participating prescription drug manufacturers. Even though state Medicaid programs can negotiate additional discounts beyond the mandated Medicaid price, because Medicaid programs cannot decline to cover most prescription drugs, their bargaining power is significantly weakened. This lack of leverage and inability to walk away, like the situation seen with Medicare Part D plans, prevents Medicaid from negotiating true value-based, indication-specific prices. Medicaid reforms to

129. For an in-depth analysis of the Medicaid Best Price Rule as a barrier to implementing value-based payment models, including indication-specific pricing, *see generally* Sachs et al., *supra* note 14.

130. *See* Sachs et al., *supra* note 14, at 8.

131. *See id.*

132. *See Medicaid Best Price Brief*, *supra* note 116; Sachs et al., *supra* note 14, at 8.

133. *See* Sachs et al., *supra* note 14, at 8-9.

prescription drug pricing would need to consider the strengths and weaknesses of the Medicaid Drug Rebate Program and the Medicaid Best Price Rule, and indication-specific pricing would worsen the problems of the current Medicaid prescription drug pricing model.

C. 340B Drug Discount Program

The 340B Drug Discount Program mandates the sale of outpatient prescription drugs to covered entities at reduced prices.¹³⁴ Covered entities include federally qualified health centers, certain disease specific programs, and publicly owned hospitals with a disproportionate share hospital percentage¹³⁵ of at least 11.75 percent.¹³⁶ There were approximately 35,000 individual covered entity sites registered by the Health Resources and Services Administration in 2016,¹³⁷ encompassing approximately 45 percent of hospitals.¹³⁸ Covered entities are able to purchase outpatient prescription drugs at significant discounts, approximately 20 to 50 percent off of the average manufacturer price.¹³⁹ This price can be no higher than the net price paid by Medicaid after rebates.¹⁴⁰ Prescription drug manufacturers are allowed to sell outpatient prescription drugs to 340B-eligible purchasers without triggering the Medicaid Best Price Rule, allowing and even incentivizing further reductions.¹⁴¹ Purchases by covered entities totaled approximately \$12 billion in 2015, with savings estimated at \$6 billion.¹⁴²

134. See *340B Brief*, *supra* note 127; MARK RILEY, WHITE PAPER: MAKING SENSE OF THE 340B DRUG PROGRAM 1 (July 2012).

135. Disproportionate share hospitals are hospitals which serve a disproportionately large number of low income and uninsured patients and are thus entitled to additional payments from the Centers for Medicare and Medicaid Services. See *Disproportionate Share Hospitals*, HEALTH RES. & SERVS. ADMIN. (May 2018), <https://www.hrsa.gov/opa/eligibility-and-registration/hospitals/disproportionate-share-hospitals/index.html>. The disproportionate share percentage is calculated by statute and described by the Centers for Medicare and Medicaid Services here: *Disproportionate Share Hospital*, CTRS. MEDICARE & MEDICAID SERVS. (last modified Oct. 4, 2018), <https://www.cms.gov/medicare/medicare-fee-for-service-payment/acuteinpatientpps/dsh.html>. The requirements for a disproportionate share hospital qualifying for the 340B program are codified in 42 U.S.C. § 256b(a)(4)(L).

136. See *340B Brief*, *supra* note 127.

137. See *id.*

138. See Blumenthal & Squires, *supra* note 122. A separate study reports that the 340B hospitals constitute 51 percent of all hospital beds in 2016. See Peter B. Bach & Rachel E. Sachs, *Expansion of the Medicare 340B Payment Program: Hospital Participation, Prescribing Patterns and Reimbursement, and Legal Challenges*, J. AM. MED. ASS'N (2018) (citing Centers for Medicare and Medicaid Services. Cost reports, fiscal-year 2017, <https://www.cms.gov/Research-Statistics-Data-and-Systems/Downloadable-Public-Use-Files/Cost-Reports>).

139. See *340B Brief*, *supra* note 127.

140. See *id.*

141. See *id.*

142. See *id.* Other studies have estimated the difference in the purchase and reimbursement for 340B hospitals in 2017 provided \$19.3 billion in profit. See Bach & Sachs, *supra* note 138 (citing

Eligibility to participate in the 340B Drug Discount Program depends on the facility, not the individual patient.¹⁴³ When an insured patient comes to a 340B covered entity and receives a prescription for an outpatient prescription drug from a physician associated with the 340B program, the pharmacy is allowed to dispense the prescription drug purchased through the 340B program but receive reimbursement through Medicare or commercial insurance at their rates.¹⁴⁴ This allows the covered entity to make a profit on the outpatient prescription drugs purchased under the 340B Drug Discount Program; this is permitted because of their status as a provider serving a large uninsured population.¹⁴⁵

The 340B Drug Discount Program, like Medicaid, calculates the discounted price of prescription drugs based on the average manufacturer price of a prescription drug,¹⁴⁶ not the average manufacturer price of a specific indication of a prescription drug. In order to implement an indication-specific pricing model, the 340B Drug Discount Program would need to modify the way it calculates the cost of prescription drugs. There has also been criticism of the 340B Drug Discount Program continuing to receive mandatory drug discounts in an indication-specific pricing scheme, with people opposing imposing additional discounts when a prescription drug is already being sold at a value-based price.¹⁴⁷ If an indication-specific pricing regime were implemented, it is possible that these discounts would be modified or repealed, undermining the efforts of the program and increasing prescription drug spending.

The high drug discounts in the 340B Drug Discount Program may incentivize inappropriate care or overuse of prescription drugs.¹⁴⁸ This is a result of the revenue 340B-eligible providers receive from the reimbursement for prescription drugs.¹⁴⁹ Some hospitals participating in the 340B Drug Discount Program are abusing the system, gaining immense profits from their prescription drug sales,

The 340B program reached \$19.3 billion in 2017—as hospitals' charity care has dropped, DRUG CHANNELS INST. (May 7, 2018), <https://www.drugchannels.net/2018/05/exclusive-340b-program-reached-193.html>). Because the program is structured such that the covered entity receives the discount directly upon purchase, the program does not cost the taxpayers and the savings directly help the covered entities to offset losses caused by their disproportionate coverage of uninsured patients and focus on local healthcare priorities, including clinics and transportation in rural and low-income areas. See Jim Martin, *We can help rural seniors and veterans by keeping the 340B drug pricing program*, THE HILL (Nov. 4, 2017), <http://thehill.com/opinion/healthcare/358771-we-can-help-rural-seniors-and-veterans-by-keeping-the-340b-drug-pricing>.

143. See *340B Brief*, *supra* note 127.

144. See *id.*

145. See *id.*

146. See *id.*

147. See Bach & Pearson, *supra* note 8, at 2504.

148. *340B Brief*, *supra* note 127.

149. See *id.*

resulting in the system receiving increased public scrutiny.¹⁵⁰ These profits and incentives for abuse could be aggravated by an indication-specific pricing regime. This is true of any fee-for-service program but would be even more likely in a system that already incentivizes inappropriate prescribing.¹⁵¹

While incentivizing prescribing high-value indications, indication-specific pricing would also incentivize overuse of drugs for high-value indications and increase overall drug spending. This could be especially prominent in certain contexts, such as cancer care. Because 340B-eligible hospitals can purchase high-price cancer drugs at deep discounts, there has already been a decrease in cancer care by community oncologists and an increase in cancer care in hospital outpatient departments, including 340B-eligible facilities.¹⁵² If these discounts continue and cancer care continues to be more affordable at 340B-eligible facilities, indication-specific pricing could further exacerbate the increase in cancer care at 340B-eligible facilities. Physicians may also be incentivized to try several different prescription drugs to treat cancer at once, whether necessary or not. Overuse and improper use would magnify an increase in drug spending from indication-specific pricing. These challenges would need to be addressed for an indication-specific pricing model to decrease, not increase, prescription drug prices and spending under the 340B Drug Discount Program.

D. Veterans Health Administration

The Department of Veterans Affairs operates its own integrated healthcare system called the Veterans Health Administration (VA), providing healthcare services to qualified members of the military after they leave active duty.¹⁵³ The VA directly provides services, including prescription drugs, through its network of medical centers, clinics, and pharmacies.¹⁵⁴

Prescription drug manufacturers are required to provide the VA and the

150. See Andrew Pollack, *Dispute Develops Over Drug Discount Program*, N.Y. TIMES (Feb. 12, 2013), <http://www.nytimes.com/2013/02/13/business/dispute-develops-over-340b-discount-drug-program.html>; Ellen Weaver & Lindsay Boyd, *States tell Congress: stop hospital abuse of federal drug discount program*, THE HILL (June 15, 2016), <http://thehill.com/blogs/congress-blog/healthcare/283491-states-tell-congress-stop-hospital-abuse-of-federal-drug>.

151. See Weaver & Boyd, *supra* note 150 (“The Berkeley findings come on top of previous research that revealed that most 340B hospitals don’t actually serve large at-risk populations. One study found that fewer than a third provide charity care exceeding the national average. And last summer, the Government Accountability Office issued a report noting that the program creates an incentive for hospitals to maximize profits by prescribing more—or more expensive—drugs. GAO then tasked Congress with removing these perverse incentives.”).

152. See *340B Brief*, *supra* note 127.

153. See *Veterans Health Administration Brief*, *supra* note 111.

154. See *id.*

Department of Defense a 24 percent discount¹⁵⁵ on the non-federal average manufacturer price.¹⁵⁶ Similar to the Medicaid Best Price Rule, if the prescription drug manufacturer sells their product to another non-federal buyer for less than that amount, they are required to sell to the VA for the lowest price.¹⁵⁷

The VA operates its prescription drug coverage as a national formulary, a list of medicines covered by the VA.¹⁵⁸ The VA provides low or no cost sharing for its beneficiaries and low costs overall.¹⁵⁹ The buying power of the VA allows it to negotiate additional discounts for many of the drugs on the national formulary, especially those drugs with significant competitors.¹⁶⁰ Further, unlike Medicare and Medicaid, which are required to cover all FDA-approved prescription drugs, the VA is not required to cover all FDA-approved prescription drugs; the ability of the VA to decline to include a drug on its national formulary gives it significantly more bargaining power than other federal payers.¹⁶¹ If prescription drug manufacturers do not comply with the mandated discounts to the VA, they are excluded from participating in most federal government health insurance programs.¹⁶² As federal government health insurers compose such a large portion of the pharmaceutical market, prescription drug manufacturers generally comply.¹⁶³

The VA would face barriers to indication-specific pricing of prescription drugs similar to those faced by other federal health insurance programs. Like the other federal programs, the VA calculates its prescription drug prices based on the average manufacturer price of the prescription drug.¹⁶⁴ The average manufacturer price does not differentiate based on the indication for which the prescription drug is prescribed. In order to implement an indication-specific pricing regime, the VA would have to change the way it calculates the price of prescription drugs. However, it may be easier in this context to track and collect the necessary data for charging an indication-specific pricing, as the VA is one integrated system instead

155. See Blumenthal & Squires, *supra* note 122.

156. The non-federal average manufacturer price is defined by statute as “the weighted average price of a single form and dosage unit of the drug that is paid by wholesalers in the United States to the manufacturer, taking into account any cash discounts or similar price reductions during that period, but not taking into account (A) any prices paid by the Federal Government; or (B) any prices found by the Secretary to be merely nominal in amount.” *Veterans Health Administration Brief*, *supra* note 111 (quoting 38 U.S.C. § 8126).

157. See Blumenthal & Squires, *supra* note 122.

158. See *Veterans Health Administration Brief*, *supra* note 111.

159. See *id.*

160. See *id.*

161. See *id.*

162. See *Veterans Health Administration Brief*, *supra* note 111.

163. See *id.*

164. See *id.* (quoting 38 U.S.C. § 8126).

of independent healthcare providers under Medicare.¹⁶⁵ It may be possible to implement an indication-specific pricing system in the VA prescription drug program, but there are still several barriers to indication-specific pricing lowering prescription drug spending in the United States healthcare system.

III. POLICY ARGUMENTS AGAINST INDICATION-SPECIFIC PRICING

The legal and regulatory barriers to implementing an indication-specific pricing scheme in federal government insurance programs are significant and worthy of consideration, but they are not insurmountable.¹⁶⁶ If accomplished, implementing indication-specific pricing in government health insurance programs would have a significant impact on and face additional barriers with the FDA approval system and incentives for physicians, patients, and manufacturers. Section A discusses the barriers presented by the FDA approval system. Section B explains the risks of liability for off-label promotion. Section C presents the arguments regarding whether indication-specific pricing would decrease prescription drug spending, concluding that an indication-specific pricing model would likely not decrease prices or improve consumers' access to prescription drugs. Section D raises ethical arguments against indication-specific pricing and other value-based pricing models.

A. *The FDA Approval System*

The current FDA approval system poses significant barriers to an effective indication-specific pricing regime. Each FDA-approved drug receives a unique National Drug Code (NDC).¹⁶⁷ This NDC is used when tracking and calculating the reimbursement price for prescription drugs. The FDA approves prescription drugs for specific indications, not general use.¹⁶⁸ This is because the safety, effectiveness, and risk-benefit analysis may differ for a prescription drug based on indications.¹⁶⁹ For example, a side effect that is harmless for one indication in one patient may be a significant risk for another indication in a different patient. Thus, when a prescription drug has more than one indication, manufacturers must consider how to gain approval for the new use.

Manufacturers have several options to gain FDA approval for new indications. One possibility is to have the new indication approved as a separate product. This

165. *See id.*

166. *See* Bach, *supra* note 18, at 1630 (“Adopting indication-[specific] pricing is thus technically feasible. Political challenges may be more substantial.”).

167. *See National Drug Code Directory*, *supra* note 78.

168. Ryan Sila, Note, *Incentivizing Pharmaceutical Testing in an Age of Off-Label Promotion*, 93 N.Y.U. L. REV. 941, 946 (2018).

169. *Id.* at 946-48.

could be done by submitting an Investigational New Drug Application¹⁷⁰ to gain FDA approval to research the new indications and then conducting full clinical trials (the traditional process for FDA approval).¹⁷¹ The newly approved indication for the prescription drug would be approved as a unique product.¹⁷² It would receive a unique NDC from the FDA, and it would be billed as a separate product by insurers. Another more common option is for the prescription drug manufacturer to file a supplemental New Drug Application¹⁷³ to update the label and gain approval for this new indication. This results in adding an indication to an already approved prescription drug. Therefore, the product has the same NDC code and must be billed and priced the same under the existing FDA regulatory scheme.

In order to implement an indication-specific pricing model, the FDA and CMS would need to develop a new or modified coding system incorporating the separate indications with approvals and reimbursements. While New Drug Applications would benefit the healthcare system by providing detailed support on the effectiveness of the new indication, there is no incentive for pharmaceutical companies to follow this route. It is time-intensive, labor-intensive, and expensive. Pharmaceutical companies are more likely to file supplemental New Drug Applications, which are quicker and require less support and expenditure. However, this results in a new indication with the same NDC as the existing product. The FDA and CMS would need to develop a system to track the different indications of individual NDC codes for reimbursement purposes. Further, physicians can prescribe these medications without the additional approvals.¹⁷⁴

170. See 21 C.F.R. § 312; *Investigational New Drug (IND) Application*, U.S. FOOD AND DRUG ADMIN. (Oct. 5, 2017), <https://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/InvestigationalNewDrugINDApplication/default.htm>.

171. *Id.* If the product is a breakthrough therapy, a cancer drug with no comparable treatment, or certain other types of treatments, the manufacturer may be eligible to gain approval by submitting an application through an Accelerated Approval pathway. See 21 U.S.C. § 356(a) (breakthrough therapies); 21 U.S.C. § 356(b) (fast-track products); 21 CFR 314.510; *Accelerated Approval*, U.S. FOOD AND DRUG ADMIN. (Sept. 15, 2014), <https://www.fda.gov/ForPatients/Approvals/Fast/ucm405447.htm>.

172. *Id.*

173. See 21 CFR § 314; *New Drug Application (NDA)*, U.S. FOOD AND DRUG ADMIN. (Mar. 29, 2016), <https://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/NewDrugApplicationNDA/default.htm>; *Off-Label Drug Promotion: Health Policy Brief* HEALTH AFF. (June 30, 2016), https://www.healthaffairs.org/doi/10.1377/hpb20160630.920075/full/healthpolicybrief_159.pdf [hereinafter *Off-Label Drug Promotion Brief*] (“Currently, a manufacturer can expand a drug’s approved indications through a supplemental New Drug Application, but performing the required clinical trials is a costly and time-consuming process, and manufacturers have little incentive to do this for drugs that are already used widely off label.”).

174. See III.B., *infra*.

These challenges are further described in the next Section.

B. *Off-Label Prescribing*

Not all indications for which prescription drugs are used are approved by the FDA.¹⁷⁵ While some prescription drugs are approved for multiple indications, many prescription drugs are only approved for one indication, even if they are commonly used for other indications.¹⁷⁶ Using prescription drugs for uses other than their approved indications is called off-label use.¹⁷⁷ Both off-label prescribing and off-label use are permitted.¹⁷⁸ However, off-label promotion of prescription drugs by prescription drug manufacturers is prohibited.¹⁷⁹ Drug company promotion of a prescription drug for a non-approved use is in contradiction with the approved labeling and qualifies as “misbranding” under the Food, Drug and Cosmetic Act.¹⁸⁰

175. See *Off-Label Drug Promotion Brief*, *supra* note 173, (“A drug is used off label any time it is administered in a way that has not been approved by the FDA . . . Providers might choose to prescribe off label for many reasons.”).

176. See Sachs et al., *supra* note 14, at 9-10 (“There are many drugs like Colcrlys, with multiple FDA-approved indications. But there are also many drugs whose secondary uses are not FDA approved, with large off-label markets.”).

177. *Off-Label Drug Promotion Brief: Health Policy Brief*, *supra* note 173 (“A drug is used off label any time it is administered in a way that has not been approved by the FDA.”).

178. See Aaron S. Kesselheim & Michelle M. Mello, *Prospects For Regulation Of Off-Label Drug Promotion In An Era Of Expanding Commercial Speech Protection*, 92 N.C. L. REV. 1539, 1546 (2014) (“Once a drug is approved, physicians have autonomy to prescribe it for any indication and patient population and at any dose, including those not described in the official labeling materials—so-called ‘off-label’ uses. Off-label uses are often medically appropriate, especially for patients with no other therapeutic alternatives where the drug’s effectiveness is biologically plausible.” (footnote omitted)).

179. See *id.* at 1544 (“The FDCA does not explicitly proscribe off-label drug promotion. Rather, it prohibits introducing any new drug or biological product that has not been approved by the FDA or is misbranded. (citing, *id.* at 1544 n.22, “21 U.S.C. § 331(d) (2012); *id.* § 355(a) (“No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application . . . is effective . . .”); *id.* § 331(a) (forbidding the introduction of adulterated or misbranded food or drugs into commerce); *id.* § 352(a) (defining false or misleading labels as misbranded drugs or devices); *id.* § 352(f) (discussing directions for use and warnings on labels).”).

180. See Kesselheim & Mello, *supra* note 178, at 1547 (“A manufacturer who promotes off-label uses risks criminal liability under the FDCA if its drug is found to be ‘misbranded.’ Drugs can be misbranded for false or misleading labeling information or labeling that does not bear ‘adequate directions for use.’ Since the only legitimate source of information about directions for use is the FDA-approved labeling information, directions provided by the manufacturer for using the drug in an off-label context are not permitted. The combination of the requirements for approval and the misbranding provision provide two avenues for restrictions on off-label promotion: a drug promoted for unapproved uses may be considered to be an “unapproved drug” for that use, or it may be deemed ‘misbranded.’ Under either statutory provision, in the FDA’s view, it can be illegal for a drug’s labeling to discuss uses of the drug that the FDA has not validated as being supported by substantial evidence.” (quoting 21 U.S.C. § 352 (2012); *id.* § 352(f)(1))).

While manufacturers are allowed to make certain statements about non-approved uses (for example in response to a request by a healthcare professional¹⁸¹), manufacturers can only negotiate reimbursement for FDA-approved indications.¹⁸² Even so, insurers in the United States, including Medicare, will generally reimburse providers for prescription drugs even when they are prescribed off-label; however, this could be because insurers cannot tell when drugs are prescribed off-label.¹⁸³ Medicare Part B is required to reimburse for off-label use of oncology drugs when there is specific published evidence supporting their use.¹⁸⁴

Off-label prescribing is relatively common, accounting for approximately 20 percent of all prescriptions in the United States.¹⁸⁵ In some cases, off-label prescribing is beneficial and necessary: some subpopulations (including children and pregnant women) often require off-label prescribing as they are generally not included as subjects in clinical trials, and thus are not included in the FDA approval.¹⁸⁶ Some specialties with few treatments for specific indications, such as oncology, result in off-label uses of prescription drugs becoming the standard of care.¹⁸⁷ Despite the benefits, there is little scientific evidence supporting the effectiveness of over 70 percent of off-label uses of prescription drugs.¹⁸⁸ Permitting drug companies to promote these uses, even allowing them to negotiate reimbursement for their use, may pose great public health risks. Off-label uses lack evidence supporting their safety and effectiveness for treating the non-indicated disease. As off-label prescribing is common absent promotion by manufacturers, permitting such promotion may result in more widespread use of drugs for off-label indications. This would lead to patients gaining access to prescription drugs

181. See *Off-Label Drug Promotion Brief: Health Policy Brief*, *supra* note 173 (“Manufacturers can communicate about off-label uses of their drugs in a number of ways. Companies are permitted to respond to unsolicited requests from health care professionals about unapproved uses and might also support independent continuing medical education activities at which off-label uses are discussed. Since the passage of the Food and Drug Administration Modernization Act (FDAMA) of 1997, companies are also permitted to distribute peer-reviewed journals and reference books that discuss off-label uses, although this practice is subject to certain limitations. In 2014 the FDA expanded this authority to include non-peer-reviewed clinical practice guidelines.”).

182. See Stephen D. Pearson, et al., *Indication-specific pricing of pharmaceuticals in the US healthcare system*, 6 J. COMPARATIVE EFFECTIVENESS RESEARCH 397, 399-400 (2017).

183. See *Off-Label Drug Promotion Brief: Health Policy Brief*, *supra* note 173 (“Payers in the United States, including Medicare, generally reimburse medications used off-label . . . in 2009, 75 percent of U.S. payers reimbursed some off-label uses of prescription drugs.”).

184. See *id.* (“Medicare Part B is required to cover anti-cancer drugs used off-label when published compendia—privately owned pharmaceutical reference guides—support their use.”).

185. THE PEW CHARITABLE TRUSTS, *supra* note 9, at 20.

186. See Patricia J. Zettler, *The Indirect Consequences of Expanded Off-Label Promotion*, 78 OHIO STATE L. J. 1053, 1078 (2017).

187. See *id.*

188. See *id.*

much faster than if manufacturers sought FDA approval through clinical trials or a supplemental New Drug Application. However, as there is a lack of evidence over the safety and effectiveness of the drug for the off-label use and off-label uses are associated with “significantly higher rates of adverse events than on-label uses,”¹⁸⁹ increased off-label use could lead to adverse events and negative health outcomes.¹⁹⁰

Linking the price of a prescription drug to its FDA-approved indications would be possible. However, while the 21st Century Cures Act expanded the ability of prescription drug manufacturers to share information on off-label uses, the FDA has only provided draft guidance, and sharing this information would likely still qualify as prohibited off-label promotion.¹⁹¹ Companies may be able to find ways to promote their prescription drugs notwithstanding the off-label promotion prohibitions. Recently, several companies have succeeded on challenging these restrictions on First Amendment grounds, asserting that this is protected truthful commercial speech.¹⁹² Companies could be extend these First Amendment challenges to the payment context, arguing that pharmaceutical companies should be allowed to negotiate with government health insurance programs using scientific evidence supporting the effectiveness of non-approved indications. The development of commercial speech doctrine does not indicate that this is likely, as courts have not yet extended First Amendment protection to unapproved indications.¹⁹³

Without requiring or incentivizing FDA approval for the additional indications, indication-specific pricing may not be a practical solution. However, if prescription drug manufacturers were incentivized to seek FDA approval for new indications, this would cause a deluge of Investigational New Drug Applications¹⁹⁴ to gain FDA approval to research the new indications; supplemental New Drug

189. *Id.* at 1079.

190. *See id.* at 1078-79.

191. *See Hayes, supra* note 19.

192. *See Zettler, supra* note 186, at 1057 (“Notwithstanding these concerns, courts, increasingly, have seemed willing to find that the First Amendment protects a broader range of off-label promotion than FDA policies have typically permitted.”); Sila, *supra* note 168, at 950 (“[the Second Circuit] it held that the effective prohibition of off-label marketing did not directly advance those interests and in any event was substantially more restrictive than the First Amendment permits.”); *Amarin Pharma, Inc. v. U.S. F.D.A.* 119 F.Supp.3d 196 (S.D.N.Y. 2015); *United States v. Caronia*, 703 F.3d 149 (2d Cir. 2012). *See generally Sorrell v. IMS Health Inc.*, 564 U.S. 552 (2011) (explaining that the First Amendment protects companies’ rights to engage in truthful commercial speech).

193. *See Zettler, supra* note 186, at 1071 (“none of the decisions following *Caronia*—in the Second Circuit or elsewhere—have extended *Caronia* to unapproved products.”).

194. *See* 21 C.F.R. § 312; *Investigational New Drug (IND) Application*, U.S. FOOD AND DRUG ADMIN. (Oct. 5, 2017), <https://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/InvestigationalNewDrugINDApplication/default.htm>.

Applications¹⁹⁵ to gain FDA approval for the indication; and applications through Accelerated Approval pathways for breakthrough therapies and prescription drugs that treat cancers with no comparable treatment.¹⁹⁶ Seeking approval for these additional indications as new indications for an existing product would make indication-specific pricing a more real possibility.¹⁹⁷ These additional studies and approvals may provide additional data on the safety and effectiveness of certain prescription drugs, especially as data on off-label uses of prescription drugs are often inadequate.¹⁹⁸ Despite the benefits of the additional research that comes with approval, FDA approval is unnecessary for patients to access these medicines and may not improve affordability. Research time and a lengthy approval process greatly delay patient access and undermine the goal of improving affordability and accessibility of prescription drugs.

Indication-specific pricing would face several regulatory and practical barriers in the FDA approval system and with the risk of liability for off-label promotion. Reforms in these two areas would be necessary in order to make indication-specific pricing feasible. Even so, these reforms may not address the end goal of prescription drug reform: decreasing prescription drug prices and spending. The possible economic effects of indication-specific pricing are discussed further in the next Section.

C. Price Effects of Indication-Specific Pricing

Experts disagree on whether an indication-specific pricing regime would decrease prescription drug spending. In general, supporters argue that indication-

195. See 21 CFR § 314; *New Drug Application (NDA)*, U.S. FOOD AND DRUG ADMIN. (Mar. 29, 2016), <https://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/NewDrugApplicationNDA/default.htm>; *Off-Label Drug Promotion Brief*, *supra* note 173 (“Currently, a manufacturer can expand a drug’s approved indications through a supplemental New Drug Application, but performing the required clinical trials is a costly and time-consuming process, and manufacturers have little incentive to do this for drugs that are already used widely off label.”).

196. See 21 U.S.C. § 356(a) (breakthrough therapies); 21 U.S.C. § 356(b) (fast-track products); 21 CFR 314.510; *Accelerated Approval*, U.S. FOOD AND DRUG ADMIN. (Sept. 15, 2014), <https://www.fda.gov/ForPatients/Approvals/Fast/ucm405447.htm>.

197. See Sachs et al., *supra* note 14, at 6.

198. See *id.*; Sila, *supra* note 168, at 951 (“critics argue that the prohibition powerfully incentivizes manufacturers to conduct clinical testing of and seek approval for more than just a single indication.”) (citing Rebecca S. Eisenberg, *The Role of the FDA in Innovation Policy*, 13 MICH. TELECOMM. & TECH. L. REV. 345, 370 (2007) (explaining that because the FDA requires that “firms conduct rigorous clinical trials before bringing their products to market and before making promotional claims . . . the FDA plays an important structural role in promoting a valuable form of biomedical R&D [research and development] that private firms are undermotivated to perform . . . while internalizing the costs of this R&D to the firms”).

specific pricing would “reduce prices for low-value indications but that prices for high-value indications will not increase.”¹⁹⁹ Many studies do not support this assertion, however. Evidence suggests that an indication-specific pricing model would not result in the desired policy incentives and effects – rational use of prescription drugs, more affordable prices for prescription drugs, and lower overall prescription drug spending. The core goal of indication-specific pricing of prescription drugs, like other value-based pricing regimes, is to make prescription drug prices better represent the value received by the patient.²⁰⁰ While maximizing value is important, it does not solve the problem of high prescription drug prices and spending.

Peter Bach, a physician and researcher at Memorial Sloan Kettering Cancer Center and a prominent supporter of indication-specific pricing in oncology care, argues that indication-specific pricing would likely decrease prescription drug spending.²⁰¹ Dr. Bach has recommended anchoring the prices of a prescription drug to its highest value indication or setting the price based on a preset value per year of life gained.²⁰² He has calculated the changes in prices of multi-indication cancer drugs based both on setting the price of the highest-value indication to the current price and by monthly price based on a cost of \$150,000 per year of life gained.²⁰³ The large variations in value by indication, he argues, demonstrate that indication-specific pricing is necessary to make prescription drug prices rationally related to value.²⁰⁴ However, his methodology presupposes that indication-specific pricing would decrease prescription drug prices, and therefore Dr. Bach’s analysis does not provide support for this conclusion.²⁰⁵

In fact, indication-specific pricing would likely increase prescription drug spending. Amitabh Chandra from the Harvard Kennedy School of Government and Craig Garthwaite from Northwestern University’s Kellogg School of

199. Chandra & Garthwaite, *supra* note 21, at 103 (citing Bach, *supra* note 18, at 1629-30).

200. *But see* Bach, *supra* note 18, at 1629-30 (“The primary reason to pursue this enhancement to the system [implementing indication-specific pricing] is to make it possible to rationalize drug pricing.”).

201. *See* Flume, et al., *supra* note 46 (“Frequent pricing critic Peter Bach recently suggested that paying by indication could save money in cancer using the example of cetuximab, which is much less effective in advanced head and neck cancer (estimated value-based price: \$470) compared with colorectal cancer (estimated value-based price: \$10,320).” (citing Bach, *supra* note 18)).

202. *See* Bach, *supra* note 18, at 1629.

203. *See id.* at 1630.

204. *See id.* at 1629 (“However, the relative findings of large differences in value across indications, and large potential shifts in pricing if the drugs were linked to value, illustrate that a change to indication-based pricing may be a necessary step toward paying rational prices for expensive drugs used to treat cancer and some other conditions, for which efficacy varies across indications.”).

205. *See id.* at 1630 (noting the methodology “Assumes the price of the drug in its most effective setting is the appropriate reference price.”).

Management have argued that indication-specific pricing would not decrease the price of prescription drugs and would therefore not decrease prescription drug spending.²⁰⁶ Instead, they argue that more effective, and supposedly higher value, indications would increase in price, making prescription drugs even more unaffordable (particularly to those who need them most). Their analysis demonstrates that “relative to uniform pricing, indication-[specific] pricing results in higher prices for patients who benefit the most, higher utilization by patients who benefit least, higher overall spending, and higher manufacturer profits.”²⁰⁷ They assert that “setting a price that more closely matches the product’s value to each customer,” is a well understood economic concept called price discrimination.²⁰⁸ Price discrimination, while resulting in a value-based price, can result in manufacturers setting the highest price that each segment of the market is willing to pay.²⁰⁹ Calculating their own indication-specific prices for cancer drugs, Professors Chandra and Garthwaite conclude that prices for high-value indications, both for prescription drugs that are currently expensive and those that are generally affordable, would drastically increase, significantly reducing patient access.²¹⁰

No pure indication-specific pricing regime has yet been implemented, so there is no real-world data to support pricing outcomes in practice. All outcomes are hypothetical and presumptive. The available evidence and incentives support that indication-specific pricing would likely increase prescription drug prices and spending. High-cost prescription drugs may be cost-effective at their current high prices: one study found that Sovaldi was cost-effective at \$84,000 per treatment.²¹¹ Relatedly, high-value prescription drugs that are currently priced low enough to be generally available would likely see drastic price increases.²¹² Indication-specific

206. See generally Chandra & Garthwaite, *supra* note 21.

207. *Id.* at 103-04.

208. *Id.* at 104.

209. See *id.* at 104 (“What would happen if the manufacturer used indication-[specific] pricing—setting a price that more closely matches the product’s value to each customer? This is a practice that economists call price discrimination, and its effects are well understood. In the most extreme version, the manufacturer extracts the most money each patient is willing to pay, leaving no consumer surplus.”).

210. See *id.* at 105 (“Absent indication-based pricing, the manufacturer could not set such a high price without having payers reduce access for patients with low-value indications—the trade-off would not be worth the lost profits. So what would indication-based pricing accomplish? For drugs currently priced so high that they’re unavailable for some indications, it expands access. Drug manufacturers would now be willing to set low prices for low-value indications, since it wouldn’t jeopardize their profits on high-value indications. But the same access-expanding pricing flexibility also allows manufacturers to increase prices for high-value indications. Currently, some treatments are priced low enough to be accessible for a wide range of indications, and it is there that we should expect the biggest price increases.”).

211. Kesselheim et al., *supra* note 12, at 859 (citing Mehdi Najafzadeh et al., *Cost-effectiveness of novel regimens for the treatment of hepatitis C virus*, 162 ANN. INTERN. MED. 407 (2015)).

212. See *id.*

pricing in many cases, especially for diseases with few alternative treatments, may not result in decreased prices and may perpetuate the prohibitively high prices leaving these drugs out of reach to many patients. Even so, some expensive prescription drugs may become more available; this would be the case for prescription drugs that are overpriced beyond their cost-effectiveness.²¹³ The low-value indications would be more available and more utilized, as their prices are lowered to match their comparative value making them more affordable to patients.²¹⁴ This increased access may have counterintuitive results in terms of healthcare outcomes; while increased access to effective treatments would lead to better healthcare outcomes, increased access to low-value indications (which are perhaps not the standard of care or not adequately effective in treating the secondary indication) would likely lead to poorer healthcare outcomes.

Without an experimental implementation of indication-specific pricing of prescription drugs, it is uncertain whether indication-specific pricing would in fact increase or decrease overall prescription drug spending and individual prescription drug prices. However, the incentives are clear. Indication-specific pricing sets higher prices for higher-value indications. Depending on an individual's prescription drug coverage, these higher prices for high-value indications are likely less affordable and less accessible as a result. Conversely, indication-specific pricing sets lower prices for lower-value indications, resulting in them being more affordable, more accessible, and used more by patient populations who receive a comparatively lesser benefit from them.²¹⁵ This could lead to an inefficient allocation of prescription drugs and healthcare resources, overall worse healthcare outcomes, and increased healthcare spending.

D. Ethical Issues of Indication-Specific Pricing

Indication-specific pricing raises several ethical concerns. First and foremost is the ethical distribution of medicines. Indication-specific pricing models suggest that indication-specific pricing in federal government health insurance programs would result in higher prices for more-effective treatments. This regime may demonstrate the value of the medication and incentivize the development of more effective treatments for diseases. In this system, when a patient seeks to buy a more effective medication to treat their disease, it would cost them significantly more money. While the intent of pricing based on value per indication may be to better allocate resources at the health system level, there are challenges to this working at the patient level. What if an individual cannot afford the most effective treatment? There could be prohibitively high out of pocket costs preventing them

213. See Chandra & Garthwaite, *supra* note 21, at 105.

214. See *id.*

215. See Chandra & Garthwaite, *supra* note 21, at 103-04.

from affording the medication that would best treat, or potentially cure, them. Either this individual will go without treatment and get sicker, later costing the healthcare system more money and having a significantly decreased quality of life, or the individual chooses a less expensive, less effective treatment, which may have poorer outcomes for the patient and result in expensive future healthcare to improve their condition. The purpose of decreasing prescription drug prices is not to justify high prices or to make them more rational; the point is that prescription drug prices are too high for patients, and thus reforms need to both rationalize prices but also make prescription drugs more affordable and accessible. Indication-specific pricing may provide ethical and optimal prescriber-side incentives (rewarding physicians for choosing the most effective, most valuable treatment) but it punishes patients who cannot afford effective prescription drugs. This is unethical and unjust.

The inverse pricing scheme has been suggested for the indication-specific model: making the most effective treatment for an indication the most affordable and therefore most accessible to patients. On the patient-side, this is ideal, assuming this low price for a high-value indication is low enough that anyone and everyone who needs it can afford it. But the physician and system incentives are less clear, and potentially against the best interests of patients and the health system as a whole. If the current physician reimbursement schemes continue, particularly in Medicare Part B, this inverse indication-specific pricing model would not incentivize physicians to provide the best course of treatment. In fact, they might be incentivized to provide less effective treatments. Patients may receive a lower standard of care from their physicians because it financially benefits their provider, and as a result the healthcare system will produce poorer outcomes and higher spending. Pharmaceutical companies would also have questionable incentives under this model. Lower prices for effective drugs disincentivizes the development of cures and effective treatments. When pharmaceutical companies identify treatments that may not be more effective than existing treatments or have little benefit to patients, the company would be incentivized to continue research and development and seek approval for several indications. From an innovation and research perspective, this is a positive: decreased off-label prescribing and additional data on prescription drugs prior to approval. However, this incentivizes companies to direct resources away from breakthrough cures and towards less effective, more profitable treatments. Innovation incentives should not support increases in pharmaceutical profits absent improvements in patient care.

The determination of value for indication-specific pricing, or any value-based pricing, also raises ethical issues. What is value? Should determinations of value be based on survival time, improved quality of life, or other outcomes benchmarks? When comparing value determinations, and therefore price determinations, across indications, there are further concerns. Is treating certain

indications considered inherently more valuable than others such that the prices are higher for effective treatments? For example, should all cancer treatments be considered more valuable and therefore inherently more expensive than a treatment for chronic back pain? Taken a step further, should a cancer treatment with little to no benefit in most patients cost more than a prescription drug that treats chronic back pain, removing virtually all symptoms, in 99 percent of cases?

While that thought experiment is an extreme (not to mention unsupported and unlikely) example, these are the kinds of determinations made in value assessments.²¹⁶ Inevitably, value assessments will incentivize companies to develop treatments for certain diseases more than others. This is one of the reasons that rare diseases (which have small populations and therefore small pharmaceutical markets) receive increased attention from the FDA in terms of accelerated approval pathways and incentives for companies that develop treatments. These may not take into account patient perspectives, particularly in terms of approved quality of life. Disability advocates commonly criticize the use of quality adjusted life years (QALYs) as a healthcare metric and raise the potential for disastrous consequences if it is used broadly and incorrectly.²¹⁷ The metric used to determine value in an indication-specific pricing regime would need to be carefully constructed to limit the discriminatory effects. Even with careful consideration, it may be impossible to remove discriminatory effects entirely. It is inevitable that an indication-specific pricing regime will prioritize certain outcome measures while disadvantaging other outcomes – and patients.

IV. ALTERNATIVE REFORMS AND RECOMMENDATIONS FOR LAWMAKERS

The incentive effects of indication-specific pricing of prescription drugs contradict the overall goals of prescription drug reform: decreasing prescription drug spending, decreasing prescription drug prices, and increasing the accessibility and affordability of high-value prescription drugs. It is thus clear that in order to decrease prescription drug spending, other models for prescription drug pricing should be pursued. Section A suggests alternative value-based pricing models that

216. See Peter J. Neumann et al., *Should A Drug's Value Depend On The Disease Or Population It Treats? Insights From ICER's Value Assessments*, HEALTH AFF. BLOG (Nov. 6, 2018), <https://www.healthaffairs.org/doi/10.1377/hblog20181105.38350/full/> (“A central question facing ICER – and by proxy all of us as health plan enrollees, taxpayers, and patients – is whether a drug’s value should depend on not only its “generic benefit” – e.g., as measured by quality adjusted life years (QALYs) gained – but also on which disease or population it treats. For example, should ICER invoke higher (i.e., more lenient) cost-per-QALY gained cost-effectiveness benchmarks in some areas (say, cancer or rare diseases) than others and, if so, on what basis?”).

217. Ari Ne’eman, *Formulary Restrictions Devalue And Endanger The Lives of Disabled People*, HEALTH AFF. BLOG (Oct. 29, 2018), <https://www.healthaffairs.org/doi/10.1377/hblog20181025.42661/full/> (criticizing using QALYs as a cost effectiveness measure in determining which drugs to exclude from formularies).

lawmakers could consider in prescription drug reform instead of indication-specific pricing. Section B introduces alternative policy interventions that lawmakers should explore to decrease prescription drug prices and spending. Section C concludes with recommendations for future legislative action.

A. Other Value-Based Pricing Models for Prescription Drugs

Value should be incorporated in the pricing of prescription drugs. Different value-based pricing models could be explored by lawmakers, but would probably not be more likely to decrease prescription drug spending than indication-specific pricing.

Average weighted pricing for multi-indication prescription drugs could be more feasible to implement than indication-specific pricing but would likely not be more effective.²¹⁸ Average weighted pricing assigns the price of a prescription drug based on the weighted average value of the prices of each indication for the prescription drug.²¹⁹ Unlike a pure indication-specific pricing regime, average-weighted pricing would not face the difficulties of pricing a drug per indication where the system does not track the indication for which a drug is prescribed or recognize differential reimbursement by indication.

However, it is unlikely that an average weighted price would have a significant impact on prescription drug prices or spending. High-value indications that are largely used would likely dominate the pricing calculation, maintaining the high costs of multi-indication prescription drugs. Thus, while average weighted pricing may avoid many of the legal and regulatory barriers related to indication-specific pricing, it would likely provide no benefits in access or affordability to patients and do little or nothing to reduce prescription drug spending.

Outcome-based payments could be another value-based model worth exploring.²²⁰ Instead of directly increasing the cost of high-value indications, outcome-based payments tie the cost of a prescription drug to the outcomes of an individual patient or patient population either by adjusting the initial price to reflect value or providing a rebate based on an individual patient's outcome.²²¹ Several prescription drug companies have entered into outcome-based contracts in the

218. See PEARSON ET AL., *supra* note 18, at 19 (“Lastly, using a single weighted-average price is far more feasible in the current environment than trying to track indication-specific use and applying different discounts to each indication. The latter approach, although a more ‘pure’ form of indication-specific pricing, is more likely to create a price that triggers Medicaid best price provisions; it also presents the greatest potential challenges for sorting out and describing to stakeholders how patients and providers are affected by different prices for different indications.”).

219. See *id.* at 11-12.

220. See Sachs et al., *supra* note 14, at 6.

221. See *id.* at 10.

private sector,²²² and recently the federal government expressed interest in experimenting with outcome-based payment models for prescription drugs for chronic disease treatment.²²³ However, the impact of outcomes-based contracts on prescription drug spending is unclear.²²⁴ One recent outcomes-based contract involving Novartis' Kymriah, a drug used for a type of leukemia, resulted in payment only if the patient received a positive response by the end of the first month of treatment; even so, the value-based, outcome-based payment was \$475,000.²²⁵

This case raises doubt as to whether such contracts in the cancer context would actually save money. If prices are set low enough and very specific outcomes benchmarks are set and tracked, it is possible that these contracts could save money. However, such terms would need to be negotiated with and agreed upon by pharmaceutical companies, which seems unlikely. More research should be done on the broader incentive effects of outcome-based payment models, specifically regarding prescription drug prices, overall prescription drug spending, and patient access to prescription drugs. Outcomes based contracts in practice may incentivize pharmaceutical companies to negotiate extremely low or easy to achieve outcomes benchmarks that do not fully demonstrate effectiveness improved quality of life in a patient. Alternatively, companies may emphasize patient perspectives to seek very subjective and potentially clinically insignificant benchmarks. Such contracts would lead to virtually certain payment to prescription drug companies and may do nothing to lower prices for many drugs if the overall value of the contract is not significantly less than the current price. If these benchmarks are not representative of the value of the drug, these prices would likely increase independent of the effectiveness of the prescription drug. With these assumed incentives, prescription drug prices and overall spending would increase, leading to poorer patient access. Unless aggressive negotiating power is given to federal government insurance programs such that they can overcome these

222. See *id.* at 10-11.

223. See Robert Saunders et al., *Medicare Accountable Care Organization Results For 2016: Seeing Improvement, Transformation Takes Time*, HEALTH AFF. BLOG (Nov. 21, 2017), <https://www.healthaffairs.org/doi/10.1377/hblog20171120.211043/full/> ("effective prescription drug use is essential to effective management of most chronic diseases that have significant population health impacts. . . . As CMMI has recently highlighted, one opportunity is implementing value-based payment reforms for drugs that share overall spending and health outcome accountability with drug manufacturers to advance the movement away from fee-for-service.").

224. See, e.g., ELIZABETH SEELEY & AARON S. KESSELHEIM, *OUTCOMES-BASED PHARMACEUTICAL CONTRACTS: AN ANSWER TO HIGH U.S. DRUG SPENDING?* 1 (Sept. 2017).

225. See Daniel et al., *supra* note 26; *Novartis receives first ever FDA approval for a CAR-T cell therapy, Kymriah(TM) (CTL019), for children and young adults with B-cell ALL that is refractory or has relapsed at least twice*, NOVARTIS (Aug. 30, 2017), <https://www.novartis.com/news/media-releases/novartis-receives-first-ever-fda-approval-car-t-cell-therapy-kymriah-tm-ctl019>.

incentives for prescription drug companies, outcomes-based contracts for prescription drugs would not decrease prescription drug prices and spending.

B. *Other Policies to Lower Prescription Drug Prices*

Other reforms should be considered instead of, or in conjunction with, value-based pricing models. Value-based pricing models have garnered great support and attention from politicians and healthcare professionals, but they only focus on one type of intervention at one point in the pharmaceutical chain – the link between the payer and the pharmaceutical manufacturer. The following list of proposed interventions is by no means exhaustive but raises a broad range of alternative policies lawmakers should consider in prescription drug reform.

Some recommended interventions would affect the interactions between payers and pharmaceutical manufacturers. One popular political talking point is allowing Medicare to negotiate prices for prescription drugs like it does for other healthcare goods and services.²²⁶ However, the Congressional Budget Office has found that Medicare negotiation would have “a negligible effect on federal spending”²²⁷ because each individual Medicare Part D already negotiates with pharmaceutical companies and because Medicare has limited ability, and thus decreased bargaining power, to exclude prescription drugs from coverage.²²⁸ Without the ability to not cover from certain drugs, Medicare Part D plans often must accept high prescription drug prices from companies.²²⁹ Additionally, Medicare negotiation could have a negative impact on the negotiating power of other federal government programs, particularly the 340B Drug Discount Program and the VA.²³⁰ While the federal government could theoretically expand its mandatory discounts to Medicare, this could still threaten the negotiating power of other federal government programs and could incentivize prescription drug manufacturers to increase prices to make up for lost revenue.

Other proposals focus on accessibility and affordability specifically from the patient perspective. Patients generally make copayments when they receive a prescription drug. Scholars have suggested basing beneficiaries’ copayments on the effective price of a prescription drug after rebates instead of the on the list

226. Kesselheim et al., *supra* note 12, at 865.

227. Juliette Cubanski & Tricia Neuman, *Searching for Savings in Medicare Drug Price Negotiations*, KAISER FAM. FOUND. (Jan. 23, 2017), <https://www.kff.org/medicare/issue-brief/searching-for-savings-in-medicare-drug-price-negotiations/>; Congressional Budget Office, *Letter to Senator Ron Wyden* (April 10, 2007), available at <https://www.cbo.gov/sites/default/files/cbofiles/ftpdocs/79xx/doc7992/drugpricenegotiation.pdf>.

228. See Sachs, *supra* note 69, at 2326.

229. See *id.*

230. See Outtersson & Kesselheim, *supra* note 90, at w834.

price²³¹ or reducing copayments by payers or through subsidies.²³² While these approaches may make prescription drugs more affordable at the time of purchase, decreasing patients' out-of-pocket spending, patients' premiums would potentially increase and effect a rise in overall federal government spending on prescription drugs.²³³ Consideration of the magnitude of the potential premium increases and federal government spending increase would have to be made in comparison to increased accessibility to patients at point-of-service.

Broader reforms of the pharmaceutical patent and antitrust regimes may have the most promise in decreasing prescription drug spending and prices. Patent exclusivity keeps the price of prescription drugs high and prevents competitors from entering into the market. Proposals have been made to limit the exclusivity period of patents, particularly limiting "secondary patents for trivial changes of a patented molecule," as well as prohibiting anti-competitive practices, including pay-for-delay agreements where patent holders pay generic companies to delay their entry into the market.²³⁴ Some scholars have even recommended using executive authority to mandate compulsory licensure of prescription drugs based on government-funded research, though this would not be a system-wide solution.²³⁵ Especially with the amount of research that is partially funded by the federal government,²³⁶ there is a social expectation that prescription drugs will be made reasonably accessible and affordable to the public.²³⁷

231. See Rachel Sachs, *Drug Policy: The Year In Review, And The Year Ahead*, HEALTH AFF. (Jan. 4, 2018), <https://www.healthaffairs.org/doi/10.1377/hblog20180103.276023/full/>.

232. Darius N. Lakdawalla et al., *U.S. Pharmaceutical Policy in A Global Marketplace*, HEALTH AFF. w138, w138 (2008).

233. See Sachs, *supra* note 231 ("As scholars have noted, patients' out-of-pocket costs may be based on their drugs' list prices, even if a Part D sponsor has negotiated a lower price. CMS has proposed passing some of those rebates on to patients; this would decrease many beneficiaries' point-of-sale costs significantly, but would potentially increase beneficiary premiums—and increase CMS' direct subsidy costs—overall.).

234. Kesselheim et al., *supra* note 12, at 864.

235. See generally Hannah Brennan et al., *A Prescription for Excessive Drug Pricing: Leveraging Government Patent Use for Health*, 18 YALE J. L. & TECH. 275 (2016); Rachel Sachs, *March-In Rights Alone Won't Solve Our Drug Pricing Problems*, HARV. BILL OF HEALTH (Jan. 12, 2016), <https://perma-archives.org/warc/HE43-R9X5/http://blogs.harvard.edu/billofhealth/2016/01/12/march-in-rights-alone-wont-solve-our-drug-pricing-problems/>.

236. See Kesselheim et al., *supra* note 12, at 863 ("important innovation that leads to new drug products is often performed in academic institutions and supported by investment from public sources such as the National Institutes of Health. A recent analysis of the most transformative drugs of the last 25 years found that more than half of the 26 products or product classes identified had their origins in publicly funded research in such nonprofit centers.").

237. David Gilman & Nathan Dowden, *Is Value-Based Drug Pricing Compatible with Pharma Innovation?*, NEW ENG. J. MED. CATALYST (Nov. 20, 2017), <https://catalyst.nejm.org/is-value-based-drug-pricing-compatible-with-pharma-innovation/> ("This innovation has occurred within the context of an implicit social contract. The U.S. government substantially subsidizes basic research and the

Critics have argued that decreasing the exclusivity periods on patents would stifle innovation, removing a key financial incentive for pharmaceutical companies to develop new prescription drugs. Studies have challenged this assertion, demonstrating that the revenue gained in the exclusivity period far exceed the costs of pharmaceutical research and development and decreasing the exclusivity period would leave adequate incentives for drug companies.²³⁸ The Lancet Commission on Essential Medicines recommended creating an Essential Medicines Patent Pool which would essentially result in voluntary or compulsory licensure for all essential medicines.²³⁹ These reforms may also challenge future innovation: while pharmaceutical companies may have adequate economic incentives to continue their work, removing some current incentives may result in companies pursuing less risky, innovative research.

One final proposal is greater transparency in the comparative effectiveness and cost-effectiveness of prescription drugs. There is little transparency in the actual prices paid for prescription drugs and there seems to be little intent on the part of the pharmaceutical industry or the federal government to increase this transparency.²⁴⁰ The Patient-Centered Outcomes Research Institute was founded to focus on cost-effectiveness research, but the Affordable Care Act “prohibited the partially government-funded research institution from considering the relative value of drugs and from using [quality-adjusted life years] as a cost-effectiveness measure.”²⁴¹ The governments of several other countries fund assessments of comparative clinical and economic value.²⁴² Currently, only non-governmental

provision of health care, and it waives its ability to negotiate directly with manufacturers about prices. In return, the biomedical industry is allowed to attempt to recoup its R&D investments during a limited post-approval period defined by the Drug Price Competition and Patent Term Restoration Act of 1984 (often called the Hatch–Waxman Act), with the expectation that drug prices will be set at a point that ensures a reasonable level of population access.”)

238. *See, e.g.*, Brennan et al., *supra* note 235, at 328 (explaining that Gilead recouped recouped its expenditure on Sovaldi and Harvoni in two and a half years, likely earning forty times the development costs in that period).

239. Sabine Vogler, et al., *How Can Pricing and Reimbursement Policies Improve Affordable Access to Medicines? Lessons Learned from European Countries*, 15 J. APPLIED HEALTH ECON. & HEALTH POL’Y 307, 316 (2017).

240. HENRY WAXMAN ET AL., GETTING TO THE ROOT OF HIGH PRESCRIPTION DRUG PRICES: DRIVERS AND POTENTIAL SOLUTIONS 30-31 (July 2017)

241. *See* RALPH MARCELLO ET AL., DELOITTE HEALTH POLICY BRIEF: GETTING TO VALUE: WHAT POLICIES ARE ON THE TABLE TO MANAGE DRUG PRICES? 5 (2016). *See also* Kesselheim, *supra* note 16, at 866 (“The Patient-Centered Outcomes Research Institute had been expected to serve in this role. It was hailed at its inception as a vehicle to promote robust comparative effectiveness research, but Congress precluded it from considering drug costs as a central focus of its work, shifting instead to patient engagement and decision aids. The institute’s reauthorization in 2019 will provide another opportunity to revisit its mission.”).

242. *See* Kesselheim et al., *supra* note 12, at 866 (“In the United Kingdom, Germany, Australia, Canada, and several other countries, government-funded technology assessment activities provide support for comparative effectiveness studies and evaluate new products in light of comparative cost-

organizations in the United States, including the Institute for Clinical and Economic Review and others, conduct such assessments.²⁴³ Lawmakers should repeal the law forbidding the government from using comparative effectiveness research to determine the relative value of treatments and inform insurance coverage and prescription drug pricing decisions.²⁴⁴ Advocating for further transparency in prescription drug pricing and the comparative clinical and economic effectiveness will encourage both rational prescription drug pricing and more informed healthcare decision-making. This is true not only for patients (knowing how much they will be paying for prescription drugs) and providers (knowing how much the drugs they prescribed will cost the patient). Greater transparency on comparative effectiveness drug prices, and in particular the discounts on prescription drugs, can aid the government in negotiating prices and improving access to patients.²⁴⁵

C. *Moving Forward: Recommendations for Lawmakers*

Ultimately, some combination of interventions is likely needed to truly control prescription drug spending and make prescription drugs accessible and affordable to all in the United States. High prescription drug prices and spending are complex problems, and reforms at various points in the healthcare delivery system could be effective. Moving forward, lawmakers should look to gain more insight on to how these various pricing regimes and other interventions would affect prescription drug spending and pricing in practice. Specifically, it is necessary to gain a better understanding of the incentive effects of such models.

Both the federal and state government have begun experimenting with alternative prescription drug pricing models. On the federal level, CMS can experiment with different prescription drug payment models, as proposed to do with Medicare Part B in 2015 and again in 2018.²⁴⁶ This plan includes a test of indication-specific pricing of prescription drugs, outcomes-based pricing, and

effectiveness analysis. The information thus generated could be used by government and private payers to help them respond to company-set prices, make determinations about formulary rules and exclusions, and educate physicians and patients about the value of medication choices.”).

243. *Id.* (“patients, physicians, and payers can turn to non-governmental organizations, such as the Institute for Clinical and Economic Review, *The Medical Letter*, the Independent Drug Information Service, Oregon’s Drug Effectiveness Review Project, and *Consumer Reports Best Buy Drugs*, which provide information on value-based choices for select medications The data generated by these groups can support lower drug prices by helping payers organize their formularies and negotiate appropriate rebates, as well as guide prescribers and patients toward more appropriate drug-use decisions.”).

244. See MARCELLO ET AL., *supra* note 241, at 4.

245. Vogler, et al., *supra* note 239, at 315.

246. See *Medicare Part B Brief*, *supra* note 64; Schrag, *supra* note 81, at 2101; Sachs, *supra* note 17.

reducing or eliminating patient cost-sharing.²⁴⁷ CMS should continue to explore interventions and implement an experiment on prescription drug pricing in its programs. The resulting data would be particularly valuable to lawmakers moving forward with reforms.

On the state level, some states are experimenting with value-based pricing models in their government health insurance programs. Massachusetts sought a waiver under Section 1115 of the Social Security Act to experiment with the prescription drug part of its Medicaid program.²⁴⁸ Its model would result in a closed formulary with at least one prescription drug covered in each therapeutic area.²⁴⁹ The proposal also included a component focusing on value: it would exclude drugs with “limited or inadequate benefit until incremental clinical value is proven.”²⁵⁰ This waiver could have resulted in Massachusetts choosing not to cover several types of prescription drugs, such as those prescription drugs approved through FDA’s Accelerated Approval Pathway.²⁵¹ Massachusetts proposed that Medicaid beneficiaries could petition to access non-formulary drugs.²⁵² The federal government initially showed interest in this and similar proposals, with President Trump’s February 2018 budget proposing a study that would allow five states to exclude FDA-approved prescription drugs from their formularies, although it did not include continuing the mandatory rebates by prescription drug manufacturers in these states.²⁵³ Even so, the Trump Administration rejected the Massachusetts proposal, reiterating the requirement that Medicaid programs cover all FDA-approved drugs.²⁵⁴ Such formularies have received criticism from the public for restricting access to drugs, not taking patient perspectives into account,²⁵⁵ using discriminatory value metrics, and devaluing the

247. See CMS proposes to test new Medicare Part B prescription drug models to improve quality of care and deliver better value for Medicare beneficiaries, CTRS. FOR MEDICARE & MEDICAID SERVS. (Mar. 8, 2016), <https://www.cms.gov/Newsroom/MediaReleaseDatabase/Press-releases/2016-Press-releases-items/2016-03-08.html>.

248. See Kesselheim et al, *supra* note 16.

249. See *id.*

250. *Id.*

251. See Manatt Phelps & Phillips LLP, *supra* note 118.

252. See *id.*

253. See *id.*

254. See Nicholas Bagley & Rachel E. Sachs, *Limiting State Flexibility in Drug Pricing*, 379 NEW ENG. J. MED. 1002, 1002-03 (2018); MaryBeth Musucemi et al., *Section 1115 Medicaid Demonstration Waivers: The Current Landscape of Approved and Pending Waivers*, KAISER FAM. FOUND. (Sept. 20, 2018), <https://www.kff.org/medicaid/issue-brief/section-1115-medicaid-demonstration-waivers-the-current-landscape-of-approved-and-pending-waivers/view/footnotes/#footnote-273141-22>.

255. Jason Shafrin & Mark Linthicum, *Patent-Centered Formularies: Steps In The Right Direction, But Challenges Remain*, HEALTH AFF. BLOG (Apr. 11, 2018), <https://www.healthaffairs.org/doi/10.1377/hblog20180404.510552/full/>

lives of people with disabilities.²⁵⁶ Taking these perspectives of value into account would be needed for states and the federal government to move forward with formularies emphasizing value.

Other states have also explored pricing regulation at the state level without a Section 1115 waiver. More than eighty pharmaceutical pricing bills were proposed in 2017 in over thirty states.²⁵⁷ New York's bill, for example, passed in April 2017, allows the state to put "limits on prescription drug costs based on their therapeutic benefits."²⁵⁸ Other states should follow and continue to experiment with various interventions to reform prescription drug spending and pricing. This further research and experimentation with various policy interventions will allow data collection so future lawmakers can make informed choices.

Moving forward, lawmakers should continue to make evidence-based proposals that will make prescription drugs more affordable and accessible to patients while allowing for decreased overall prescription drug spending and continued innovation incentives.

CONCLUSION

The skyrocketing prices of prescription drugs and increasing federal drug spending pose significant threats to affordable healthcare in the United States. An indication-specific pricing regime for prescription drugs in federal health insurance programs would neither decrease overall prescription drug spending nor improve accessibility and affordability of prescription drugs for individual patients. The current legal and regulatory framework in Medicare, Medicaid, the 340B Drug Discount Program, and the Veterans Health Administration pose several challenges to implementing any value-based pricing scheme, especially indication-specific pricing. The FDA approval system and the risk of off-label promotion liability also stand in the way of implementing an indication-specific pricing regime in the United States. Additional policy effects and ethical considerations would also have to be made in reforming the prescription drug pricing system in order to protect patients' access to medicines. The barriers to indication-specific pricing may not be insurmountable, but substantial system modifications would have to be made for it to be a realistic option. Even with these

256. Ne'eman, *supra* note 217.

257. See BERMAN ET AL., *supra* note 14, at 1. Particularly innovative bills were passed in Maryland, New York, and Nevada. See *id.* See also Theodore T. Lee et al., *Legal Challenges to State Drug Pricing Laws*, 319 J. AM. MED. ASS'N 865, 865-66 (2018) (discussing legal challenges to state laws to control prescription drug prices); Fran Quigley, *On Drug Pricing, States Step In Where Washington Fails*, N.Y. TIMES (Feb. 27, 2018), <https://www.nytimes.com/2018/02/27/opinion/drug-pricing-states.html> (discussing state efforts on prescription drug price reform).

258. See Thomas J. Hwang et al., *Value-Based Pricing and State Reform of Prescription Drug Costs*, 318 NEW ENG. J. MED. 609, 609 (2017).

modifications, indication-specific pricing would likely not decrease prescription drug prices or overall spending.

As the United States continues to pursue healthcare reform and tackles the problem of unaffordable prescription drug prices, value-based pricing regimes should not be disregarded. Other interventions should be considered to decrease prescription drug prices and spending. Moving forward, lawmakers must explore these potential solutions and focus on affordability and accessibility. The problem of high prescription drug prices and spending is complex and multi-faceted, and any change to the current regime will have impacts on the insurance system, patient access, healthcare system spending, healthcare outcomes, and pharmaceutical innovation.

Any reform to prescription drug pricing and spending must prioritize patient access. Indication-specific pricing may create more problems while failing to increase the accessibility and affordability of drugs. The current system of prescription drug pricing is unethical and unaffordable. Reforms must not perpetuate the problem.

